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Master Thesis
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Coastal Commons and Codified Commodities:

Exploring The Role Of Intellectual Property Rights On Genetic Resources In Norwegian Biotechnology Innovation Systems

Erlend Stien Grimsrud

Foreword and acknowledgements

This thesis concludes two highly interesting years at the Norwegian University of Life Sciences in the international master program of Aquaculture Science. It is also a product of many prior years of academic, professional and personal dedication to the resources of the seas. I wish to express my sincerest gratitude to the people I have met along the way: instructors, colleagues, and other acquaintances - helping me forward by opening new doors of inspiration and *unprotected* knowledge. A special thanks to my supervisor, Bernt Aarset, for boldly welcoming and supporting the request of a motivated student of a primarily *biological* discipline to do research on highly complex *political, social and economical* aspects of intellectual property in marine biotechnological innovation systems. Our discussions and his guidance exceeded my best expectations, and inspired a personal interest in the work of this thesis beyond academic commitment. I am also grateful for the information and advice of Ingrid Olesen in the progression of the thesis, and for giving me access to data resources. Informants and respondents of the research have been welcoming and very helpful. Thank you very much for insight to your worlds and input to my thesis!

Finally, the social ballast of dear family and friends has been highly valuable in my best attempt of navigation through these murky seas of protected knowledge in Norwegian biomarine innovation systems.

Erlend Stien Grimsrud

Abstract

Exploitation of the extensive Norwegian marine resources has entered the era of modern biotechnology- the third strategic technology in the post-war period-with the potential to transform our future, following nuclear- and information technology. Commercial biotechnological application of novel compounds and gene expressions found through marine bioprospecting is at a novel industrial stage, whereas the established aquaculture industry calls for biotechnical solutions to further improve production efficiency and solve biological challenges of increased seafood production. As key components of the national innovation policy for the knowledge based economy, both industries are set in highly complex innovation systems of academia and government. Further complexity should be considered, as the sources of knowledge are genetic resources, considered to be *commons* or *public goods*. Traditional innovation literature emphasizes proprietary rights to knowledge as the key driver of high technology innovation. But in the biotechnological sector and when utilizing genetic material, such rights have received much criticism due to aggressive privatisation.

The need for industry-specific knowledge protection strategy regimes has not yet received much attention in Norwegian marine innovation systems. Through the explorative, abductive approach of qualitative research methodology, this study explores several dimensions of intellectual property that can be observed in these systems, and examines their effect on performance of the innovation system. Two separate innovation systems and industries, aquaculture and marine bioprospecting, are examined by survey response analysis and case study interviews to gain perspectives on the implications of knowledge protection. Finally, intellectual property regimes intended to balance proprietary right incentives and the public good concerns are assessed on the basis of respondent insight and literature review.

TABLE OF CONTENTS

List of figures:

List of tables:

Abbreviations and terms:

ABS:	Access and Benefit Sharing
CBD:	UN Convention on Biological Diversity
DOFI:	Disclosure of Innovation
	(Declaration form for a potentially protectable discovery)
de facto:	*lat. term;"*Concerning fact" – How it works in practice (not *de jura*)
de jura:	*lat. term*; "Concerning law" – How the law intends it to work
EPO:	European Patent Organisation
FAO:	Food and Agriculture Organisation of the United Nations
FUGE:	Public Functional Genomics R&D funding program
HAVBRUK:	Public aquaculture R&D funding program
IP:	Intellectual Property
IPR:	Intellectual Property Rights
IS:	Innovation System
MTA:	Material Transfer Agreement
MRA:	Norwegian Marine Resources Act of 2009
NSI:	National System of Innovation
R&D:	Research and Development
MELD.ST.:	Stortingsmelding (no); *Government white paper (transl.)*
SMTA:	Standard Material Transfer Agreement
TRIPS:	Trade Related aspects of Intellectual Property Rights
TTO:	Technology Transfer Office
	Facilitate commercialisation of scientific results of University research
WIPO:	World Intellectual Property Organisation
WTO:	World Trade Organisation

1 INTRODUCTION AND CONTEXT

1.1 CONTEXT

Traditional exploitation of Norwegian marine genetic resources, by wild-stock harvest and aquaculture for consumer markets, is expected to be supplemented by a variety of high technological industries and applications such as bio-prospecting, genetic technology, biomedical/bioactive synthesis, neutraceuticals and biofuel production (DKNVS report, 2006). Increased global demand for nutritious marine protein, coupled with declining fish stocks, challenges in aquaculture production and the transition towards a global seafood market suggest a need for innovation and efficiency measures in the marine sector by biotechnological advances and consolidation with larger capital-intensive organisations ((Asche et al., 2013b, Asche et al., 2013a).

The Norwegian seas have entered the era of modern biotechnology, stated to be the third strategic technology in post-war period with potential to transform our future life, following nuclear- and information technology (Gaskell et al., 2000). New high value markets have emerged by advanced processing of new species and by-products of the fisheries and aquaculture sector. Application of unique compounds and structures, genetic expressions and biological activity to the vast diversity of organisms in the seas is believed to accommodate resolutions to social, technical and environmental challenges within the biomarine industries and in our society as a whole.

To address and emphasise the evolving marine industry, the Norwegian *Marine Resources Act* was entered into force 1. January 2009, replacing the outdated *Sea Water Fisheries Act of 1983 (pers. transl.)*. The new Act regulates how, where, when and how much of all the living marine resources can be harvested. By widening the scope to cover all living marine resources including marine genetic material, it is also the first Norwegian act regulating outtake of any genetic material. The objective of the Act ensures that management of living marine resources and genetic material derived from them is sustainable and socially and economically profitable. Section 7 paragraph 2 address the importance of appropriate allocation of resources, which can help to ensure employment, maintain settlements in coastal communities and promote

optimal utilisation of resources that are well adapted to marine value creation, markets and industries. The Act states that the resources cannot be privatised.

Publicly funded biotechnological research and development programs modelled on open science, has been a key contributor to scientific advancement in this sector. Now the R&D is set in several national and regional systems of innovation, which include industry actors, to improve both upstream and downstream innovations (Doloreux et al., 2009). In these systems, the need for industry-specific knowledge protection strategy regimes has not yet received much attention (Olesen et al., 2007, Tvedt, 2010, Tvedt, 2011). Innovation theory emphasizes the proprietary rights to knowledge production as one of the main drivers of commercially innovative organisations in high technology sectors (Lai, 1998, Greenhalgh, 2010). In the biotechnological sector and when utilizing genetic material, such rights and broad scoped patents in particular, have received much criticism due to the aggressive privatisation of innovation protection (Benson, 1986, Hemphill, 2010, Deibel, 2013), described as "the tragedy of the anti-commons" (Buchanan and Yoon, 2000, Heller, 1998).

1.2 NORWEGIAN BIOMARINE SECTOR

1.2.1 INNOVATION POLICY AND INSTITUTIONS

The Norwegian coastline, including fjords and islands, measures 103.000 km in total, making it the Worlds second most extensive by country, superseded only by Canada. The Gulf Stream distributes warm nutrient rich seawater along most of the western- and northern coastline, which give rise to an abundance of marine biodiversity and biomass (Dodet and Malmcrona, 1991). Harvesting of marine biological resources has thus contributed greatly to the wealth of the national and regional economy. Marine policy has been important both for the management of resources and development of new technologies to fully utilise the potential of the coastal areas.

Traditionally, innovations within harvesting technology, aquaculture technology, seafood processing and marketing have been funded, fully or partly, by regional development funds and public R&D consortia to maintain a competitive and profitable marine industry. Marine innovation is embedded in the research activity of most Norwegian universities and relevant public research institutions. Funding and administration of marine research activity is provided by the Research Council of

Norway (public), Innovation Norway and various regional development funds (public) in additional to industry cooperative funds such as the Norwegian Seafood Research Fund (FHF).

In 2013, the Norwegian government published the white paper outlining the future seafood policy; *"The Leading Seafood Nation in the World"* (Meld. St. 22, 2012-2013 pers. transl.). Sustainability, profitability and knowledge are here noted as the pillars of success, where marine innovation is highlighted. Aquaculture and biotechnology compromise two of 7 large strategic programmes of the Research Council of Norway. *HAVBRUK* and *BIOTEK* are further included in the *HAV21* strategy.

1.2.2 SEAFOOD AND AQUACULTURE

Seafood is currently Norway's second largest export commodity, after petroleum (oil, gas etcetera). A recent study of the total value creation of the supply chain in the Norwegian seafood sector estimated an approximate NOK 46,5 billion contribution to the gross domestic product (GDP) and approximately 47.400 full-time equivalent (FTE) positions and production value of approximately NOK 156 billion (Sintef report A26088).

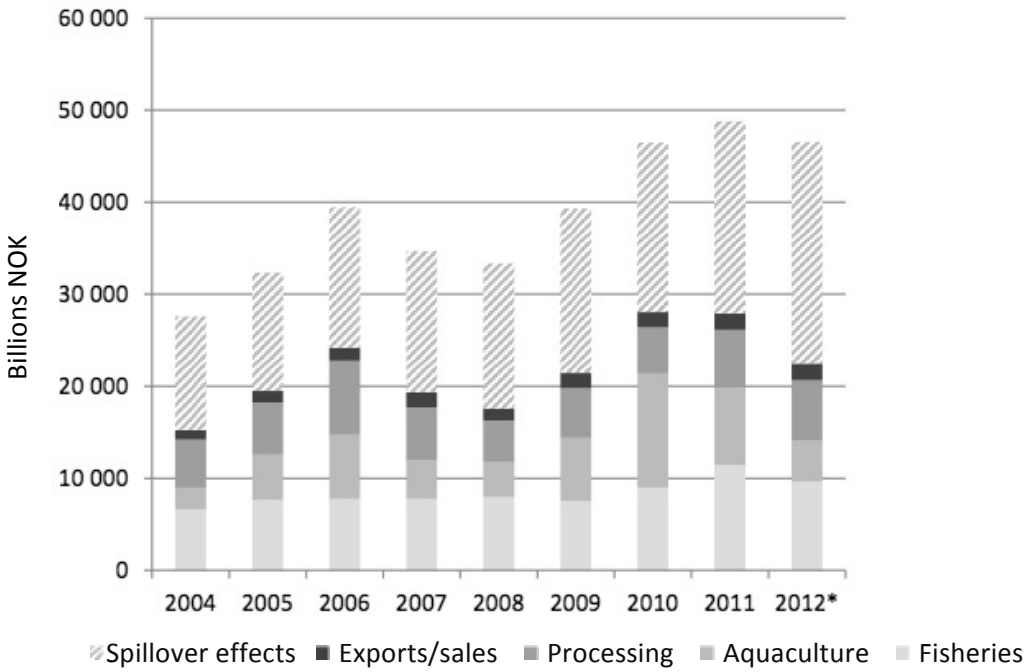

Figure 1.2.1.a Annual total contribution to GDP by the complete value chain of the Norwegian seafood sector (SINTEF report A26088)

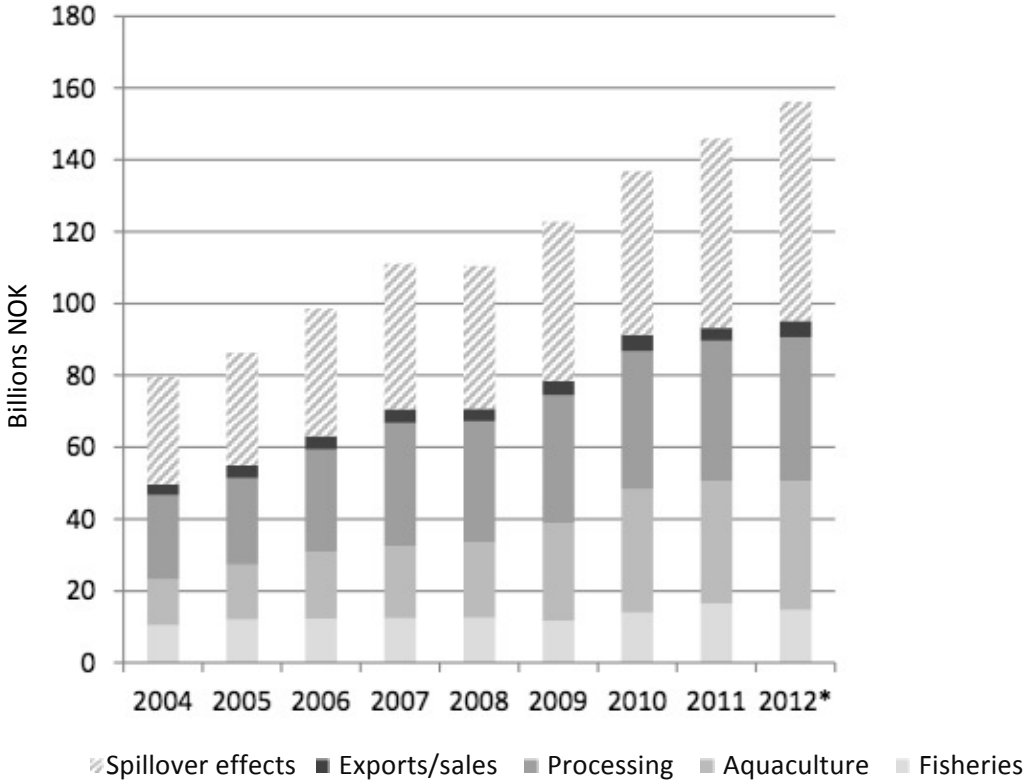

Figure 1.2.1.b Annual total production value by the complete value chain of the Norwegian seafood sector (SINTEF report A26088)

The export value of wild stock fisheries was recently superseded by aquaculture production, defined by the FAO as "*the farming of aquatic organisms in inland and coastal areas, involving intervention in the rearing process to enhance production and the individual or corporate ownership of the stock being cultivated*" (FAO Glossary, internet). Salmonid fishes, such as Atlantic salmon and rainbow trout, are the main contributing species to the Norwegian export with an approximate value of $ 5,7 billions by 2012 (Norwegian Diractorate of Fisheries and Aquaculture Statistics).

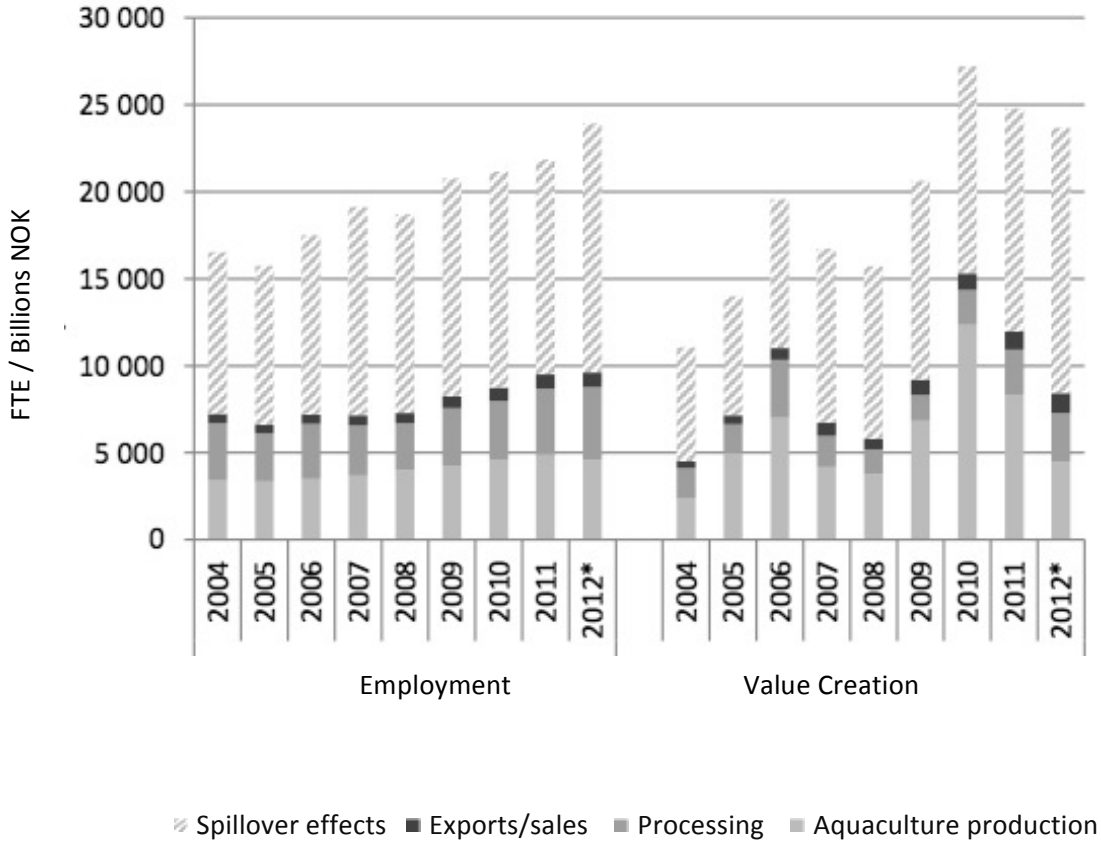

Figure 1.2.1.c Annual employment and value creation by the Norwegian aquaculture sector (SINTEF report A26088)

The industry has experienced rapid growth since the early start-ups in the 1970s, and is today technologically and biologically advanced. Much of the advances can be accredited strategic marine research policy and funding to stimulate innovation to solve biological and technical constraints in the industry and secure regional development in coastal Norway. Historically, the efforts can be characterized as applied research from knowledge generated in agricultural sciences, biological sciences and resource economics. Innovations have been initiated at the desperate urge to solve critical problems (Raa, 1990, Asche et al., 2013b). The seafood industry in general, and aquaculture in particular, still has a number of challenges to increased production, which can only be addressed by generating competence and technologies through further research and innovation (Asche et al., 2013a). In addition to the economic challenge of global market adaptation by cost-efficiency measures, the salmon farming industry must innovate to solve serious challenges related to fish diseases and parasites, animal welfare, environmental impact and marine ingredients

dependency, which are now the main barriers to further growth and significant contributions to the critical public opinion of the industry (Chu et al., 2010).

The aquaculture related disciplines of animal breeding (genetics), fish health, feed production (nutrition) and processing (technology) have all benefited from biotechnological research, and is commercialised in multinational aquaculture enterprises such as AquaGen, EWOS, Pharmaq and Salma Brands. Much of these important technical advances, by aquaculture research results, have been initiated, funded and conducted publicly. To further improve production efficiency in the industry, public financing for R&D-projects in the aquaculture sector is still required for at least two reasons (Asche, Roll & Tveterås, 2012):

1. *There is a significant financial risk associated with R&D in the form of significant investments that often do not give return, as they do not lead to the innovation of initial interest/aim of research*
2. *There are significant "collective good" problems, i.e. private companies behind R&D investments can only appropriate parts of the financial rewards when they succeed in their innovation. Much of the rewards accrue to end customers – usually fish farmers.*

Asche et al (2012) argues, however, that if R&D-based innovation is to become more effective in Norway, it is necessary to involve large companies with great resources in the financing and provision.

1.2.2.1 AQUATIC ANIMAL BREEDING

Animal breeding is selection of breeding candidates with the aim of improving the fish over several generations by means of genetic variation according to the breeding goal. In 1975, at the very early stage of salmon aquaculture, a strategic breeding program was initiated by researchers at the Norwegian school of Agriculture science (Gjedrem, 2010). This effort is regarded as one the most important contributing factors to the success of the industry today (Gjoen and Bentsen, 1997). Gjedrem (2007) estimates the value of a selective breeding program of fish by cost-benefit analysis to 1:15. The optimal financial distribution of the benefits and costs of such a program is however little studied. Today, much of the genetic improvement efforts are utilizing various forms of bioinformatics as tools for research and development.

These include genomics and marker assisted selection. Olesen, Rosendal et. al (2007) presents structures of access and protection of genetic resources in aquaculture, and review the various protection strategies such as MTA, patents, biological protection (reproduction), secrecy, sui generis and more in the scope of access regimes. It is currently a debate whether genetic improvement of animals should be regarded as bioprospecting (Reply of The Norwegian Bar Association to hearing paper – the bioprospecting act, 2013), and thus subject to the legislations now being formed (Hearing paper – the bioprospecting act, 2013). Here, successful biotechnological industries based on utilisation of organisms- or information gained from genetic material found in Norwegian seas are suggested to pay significant royalties of their profits to the Norwegian state. Such a royalty could be dramatic for the full value chain of the aquaculture sector, as it is set in a global market of low margins.

1.2.3 BIOPROSPECTING

This paper will discuss biotechnology in a broad context by the definition of the United Nations convention on biological diversity (CBD); "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". Where the biological systems, living organisms or derivatives thereof originate from the oceans, it will be addressed as marine biotechnology. Like other evolving technological industries, biotechnology is highly innovative, with great efforts to every valuable discovery. Intellectual property is therefore vital in knowledge creation to be a head of competitors (Greenhalgh, 2010).

All though much innovative interest is set on marine biotechnology in Norway, the industry is still small compared to the seafood industry. Publicly funded research aim to find the right potential for an industry, and create a framework for innovation and resource utilisation. This contrasts the large commodity production of the aquaculture sector, which looks to biotechnology to solve "internal affairs" and improve production efficiency.

The Norwegian ministry of fisheries and coastal affairs, and the Norwegian ministry of the environment defined bioprospecting as *"purposeoriented activities, systematic exploration, collection of biological samples and identification of interesting and*

bioactive compounds or genes in organisms with potential for commercial exploitation." (Hearing paper; the bioprospecting act 2013).

1.3 TOPIC RELEVANCE

Evolving industries adapt to institutional environments. Traditional means of intellectual property rights, patents in particular, in biotechnology is highly controversial (Adler, 1984, Barpujari, 2010, Calvert, 2012, Hemphill, 2010, Rai, 2011, Scott, 1998) due to the monopolizing and exclusive nature of IP and the sovereign nature of the novel biological organisms and derivatives, stated to be global commons (Heller and Eisenberg, 1998, Runge and Defrancesco, 2006). IPR of genetic material utilized in food producing industries also receive much criticism with similar arguments, highlighted by the case of seed protection strategies of the *Monsanto* agriculture corporation (Tvedt, 2007).

1.4 OBJECTIVE OF THE STUDY, DESIGN AND THESIS OUTLINE

Commercial strategies and institutional forces encompass and construct biotechnological innovation systems. This thesis will seek to understand the main contributing forces to the use of IPR in two seperate Norwegian biomarine innovation systems and discuss the performance of current IPR management in the systems. Moreover, attitudes and social phenomena of IPR management within the biomarine sector will be studied to further understand the position intellectual property holds as transfer of knowledge and mediators of collaboration between the modern harvesters of the Norwegian marine genetic resources. Findings from survey data and a relevant case study will be discussed in the light of a conceptual framework of innovation theory, game theory and institutional theory as well as personal insight to the industry. Finally, findings from this study will present topics to the discussion on National industry-specific IPR policies.

1.4.1 RESEARCH QUESTIONS

1. ***Which factors are dominating in IPR management strategies in Norwegian marine biotechnological innovation systems – and what are their effects on the performance of the system?***
2. ***How are current IPR regimes in the systems balancing innovation incentives and the public good of the marine commons through publicly funded knowledge production?***
3. ***Which concerns should be addressed by a future industry-specific IPR regime in these innovation systems?***

1.5 SCOPE AND LIMITATIONS OF THE STUDY

To fully explore the complex topic of research within the publicly funded R&D programs in this paper, I have chosen an approach of wide scope. Protection of knowledge and innovation systems performance touches several disciplines of science and research, such as law, philosophy/ethics, micro/macroeconomics and biological technology, organisational theory, many of which are not within the scope of my expertise. Hence, this wide scoped exploratory approach is also the main limitation of the study, as it suggests findings and patterns rather than conclude. The research design is structured to gain insight to a wide range of questions, and possibly bring forward some new. At the end of this research, I can confirm that several more descriptive designs have come to mind that would better analyse specific components of this study.

The study is limited to publicly funded R&D in innovation systems of the biomarine sector, although industrial actors commercial strategies ("outside" of the system) will be discussed. Furthermore, only innovations where the source knowledge and technology are genetic resources will be examined.

1.6 POLICY RELEVANCE

The Research Council of Norway contributes about 1/6 of its total budgets directly to commercial actors R&D activities. In addition, collaborating universities, institutes and corsortia with private actors receive much of the public funds, which are to spur

innovation and contribute to the national economy and "welfare state". But *are the regimes of proprietary rights of innovations designed to ensure a fair distribution of benefits of the innovations? What role should the protection- and transfer of public funded knowledge to private innovation play?*

There is currently a growing political, academic and commercial interest in marine biotechnology in Norway. The political interest is highlighted by the Strategy on marine bioprospecting as a source for new and sustainable value-creation, "Marin bioprospektering – en kilde til ny og bærekraftig verdiskaping", and its revised strategy, which is on hearing in the progress of this study. It is a political strategy to increase academic and commercial use of material found through marine bio prospecting by making such resources accessible.

Databases of bioinformatics and physical biobanks (s.a. salmon genome project, MARBANK, BioBank) can possibly unite the interests of academia, industry and the public innovation strategy of the Government whilst securing biodiversity and environmental concerns. Here, inclusion of the industrial actors' interests is essential for the legitimacy of the policy and thus the successful commercial applications of the new technology.

In the duration of this thesis, the European standard CEN/TS 16555-1 of Innovation Management Systems is being implemented in the Norwegian innovation policy (Teknisk Ukeblad, internet). The initial report, expected published in fall 2014, will include a best practice guideline for IPR management in general innovation systems. In biotechnological innovation systems, however, more industry-specific guidelines should be included. This paper will hopefully contribute to the discussion of best practice of the coastal commodification.

2 CONCEPTUAL FRAMEWORK

This section will present relevant theory to enlighten the research questions. First, introduction to the fundamental theory of innovations and further models of dynamic relational innovation systems and knowledge production and flow will set the premise for the systems of study. The role of intellectual property in the systems will here be embedded. Furthermore, behavioural theories on exploitation of limited resources will be presented with technical and ethical aspects of knowledge protection and intellectual property. To further elaborate the role of social relations and institutional forces found in organisations and innovation systems, models of neo-institutional theory conclude the conceptual framework for studying these complex systems.

2.1 INNOVATION THEORY

There are several definitions of the term and concept *innovation*. Joseph Schumpeter is however best recognised for his definition and his studies on the significance of innovation in economic change (Andersen, 1993). According to Schumpeter (1934) innovation is defined as:

- The introduction of a new good, that is one with which consumers are not yet familiar, or of a new quality of a good.
- The introduction of a new method of production, which need by no means be founded upon a discovery scientifically new, and can also exist in a new way of handling a commodity commercially.
- The opening of a new market, that is a market into which the particular branch of manufacture of the country in question has not previously entered, whether or not this market has existed before.
- The conquest of a new source of supply of raw materials or half-manufactured goods, again irrespective of whether this source already exists or whether it has first to be created.
- The carrying out of the new organization of any industry, like the creation of a monopoly position (for example through trustification) or the breaking up of a monopoly position

Innovation literature emphasises furthermore innovation as a foundation for maximizing profit for shareholders, mainly through advances of technological application based on knowledge. Although this literature cannot be described as homogeneous, traditional innovation theory is here mainly related to a form of economic theory with a rational-instrumental approach (Greenhalgh, 2010). This traditional concept of innovation is presented as a linear flow in an enterprise from an idea through conceptualisation (processing of the idea) to the end market and society. Modern theory, however, presents the flow as a dynamic innovation system (Katz, 2006, Isaksen and Karlsen, 2010, Siegel et al., 2003, Adger et al., 2005, Lundvall, 2007). In this system, innovation flow is defined by the interplay between the actors, financial instruments and policy makers, and is thus complex (Katz, 2006, Greenhalgh, 2010). Section 2.1.2 will present innovation systems at national and regional levels. Creation-, flow- and application of information and knowledge are key variables to the performance of an innovation system (Agrawal, 2001, Siegel et al., 2007). This level of complexity is therefore of particular interest for the essence of this thesis.

2.1.1 KNOWLEDGE, INNOVATION AND ROLE OF INTELLECTUAL PROPERTY

Jensen et al (2007) distinguishes between two modes of innovation:

- ***Science, Technology and Innovation (STI)***
  is based on the production and use of codified scientific and technical knowledge
- ***Doing, Using and Interacting (DUI)***
  is more dependent on informal learning and experience-based knowledge (know-how).

There are many examples of both modes in aquaculture and marine biotechnology. However, in business industries in general, it is argued that the STI-based innovation processes has led to more radical innovations than DUI-based innovation processes (Jensen et al, 2007). In both modes, it is considered important for organisations to protect the generated knowledge from competitors (Greenhalgh, 2010), in order to gain returns on the investments for knowledge production, and to create- or break down a monopoly situation, as described by Schumpeter's (1934) definition of innovation point 5. By allowing codified information flow, the coded knowledge can

also contribute to incremental innovations by actors in related industries. The generated knowledge can be secured by intellectual property in various forms. STI-modes of innovation are generally more active in securing the rights to intellectual property, as codification of knowledge can ease the flow of information to competitors (Agrawal, 2001, Jensen et al., 2007). Section 2.2.2-2.2.4 in this thesis will further present the technical nature of intellectual property, and the further rights of utilisation (IPR).

2.1.2 *National innovation systems and* the triple helix *of institutions*

An *innovation system* is a wide scoped conceptual framework for the complex sets of relationships between the many actors involved in-, and around innovation processes (Andersen et al., 2002, Lundvall, 2007). A systems' scope can geographical; national, regional, "inter-regional and local or sectoral/technological (Lundvall et al., 2002). Modern knowledge society includes academia in innovation systems, whereas the earlier industrial society was composed of a government-industry dyad (Etzkowitz and Leydesdorff, 1996, Ranga and Etzkowitz, 2013). Academia and industry now have interactive roles as mutual knowledge producers for the knowledge based economy, and the government is partly administering funding and regulations through its innovation policy.

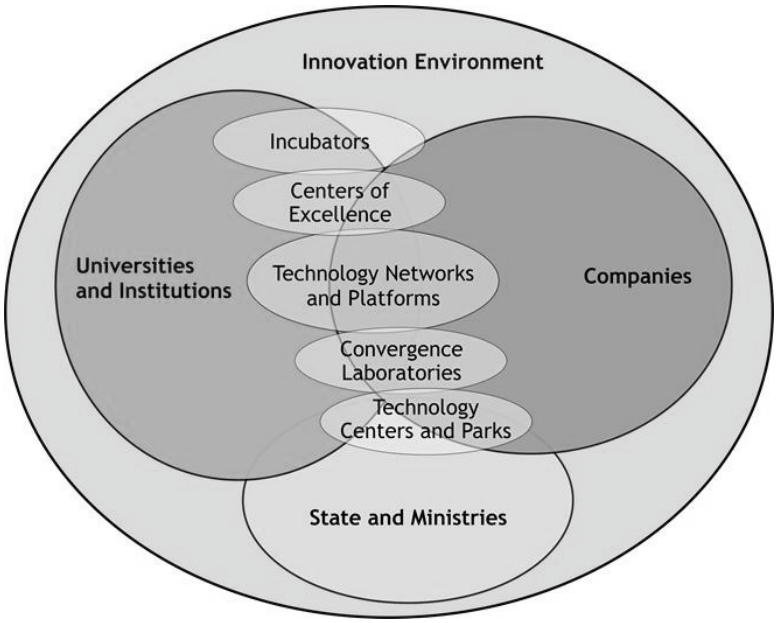

Figure 2.1.2.a Main institutions in a national innovation system environment

Empirical findings of researchers at Stanford University gave rise to *the Triple Helix* model as an analytical concept of innovation systems, and also the framework for several regional and national innovation systems today, including many of those in Norway (Strand and Leydesdorff, 2013, Isaksen and Karlsen, 2010). The models' etymology is three *(triple)* spirals (*helix*) representing academia, state and industry that spin intertwined to form a progressive model of innovation that captures multitudal and mutual relations of inputs and output in the capitalization of knowledge (Etzkowitz, 2003).

Cooperation between academia and industry was previously based on a linear innovation model where academic knowledge would be a long-term contribution to the economic market(Etzkowitz and Leydesdorff, 1996). Today, such systems are considered as interactive innovation models, such as the Triple Helix model. Such interactions should promote increased innovation performance at a regional level when the system and the actors are configured right (Etzkowitz, 2003). Triple Helix can thus be considered as a model for regional cooperation to strengthen innovation processes between the three actors. This is in contrast to traditional practice, where each group has collaborated interrelated, but not- or very limited between groups.

Learning effects, and thus innovation systems performance, from Triple Helix cooperation depends on the contribution and activity of each of the three players.

Etzkowitz and Leydesdorff (2000) determine three configurations of institutional spheres and their relationships in innovation systems;

1. *Statist* configuration, where government plays the lead role, driving academia and industry, but also limiting their capacity to initiate and develop innovative transformations
2. *Laissez-faire* configuration, characterised by a limited state intervention in the economy, with industry as the driving force and the other two spheres acting as ancillary support structures and having limited roles in innovation: university acting mainly as a provider of skilled human capital, and government mainly as a regulator of social and economic mechanisms.
3. *Balanced* configuration, specific to the transition to a Knowledge Society, where university and other knowledge institutions act in partnership with industry and government and even take the lead in joint initiatives (Etzkowitz

and Leydesdorff, 2000). This balanced configuration offers the most important insights for innovation, as the most favourable environments for innovation are created at the intersections of the spheres.

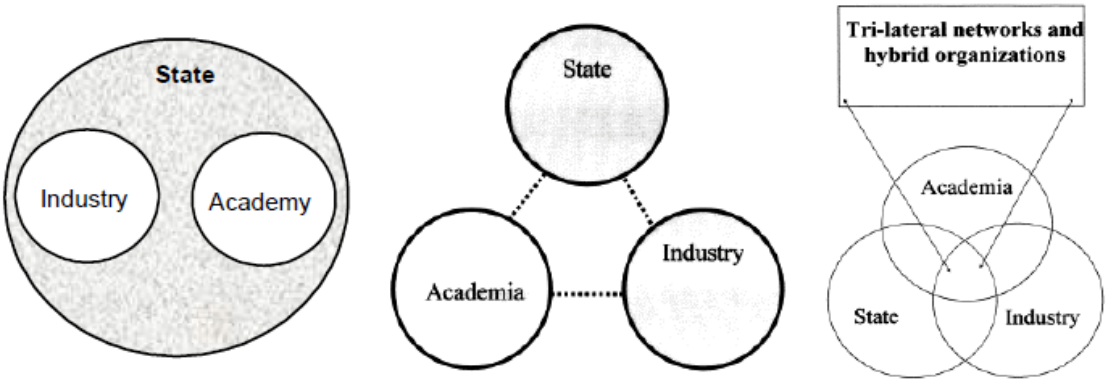

Figure 2.1.2.b Three modes of institutional spheres and relationships of in innovation systems: *statist (left), laizzes-faire (middle) and balanced (right) configuration* (Etzkowitz and Leydesdorff, 2000).

The vectors of relationships between actors of innovation systems can be both formal and non-formal. From findings of survey-based research, "social relations" are considered as more important than "non-social", and in particular the commercialization of research-based knowledge through licensing regarded as a less important channel connection between academia and industry (Cohen and Levinthal, 1990, Isaksen and Karlsen, 2010). For the regulatory management of innovation systems, however, IPR and licencing play are considered to play highly important role.

	«Social»		*«Non-social»*
	Relations of cooperation	**Personal mobility**	**Knowledge transfer**
Formal	Consortia Partnership agreements Contract research	Spin-offs Tutoring contracts Staff exchange contracts	Commercialisation of research based knowledge: IPR Licencing of patents, MTA etc.
Non-formal	Networks	Consultancy contracts, Scientific presentations, Other means of dissemination and externally oriented activity	Scientific publications Other publications

Table 2.1.2 Relations of cooperation between academia and industry

Encouraged by governments' national innovation policy, some public research institutions consider their best option of utilising research results and technology of potential commercial interest is by securing it through formal intellectual property rights (Patents, MTA etc.). The logic behind it is that industry, to make investments in further development profitable, must be guaranteed exclusive rights to the technology (Colyvas and Powell, 2006). This process of commercialization is usually evaluated and facilitated by technology transfer offices (TTO) that have been made responsible for securing the rights as well as to find commercialization partners (Siegel et al., 2003). In addition to societal benefits to the economy considered in the innovation policy, such an approach is also seen as a potential source of income for public research institutions. Options of transfer and licencing of IPR is presented in section 2.2.3.2.

Such transfer events of IPR can also be observed in the triple helix model. IPR can be perceived as social coordination mechanism within innovation systems in three ways (Etzkowitz, 2003) (Figure 2.1.2.c):

1. *Wealth generation incentive by the industry*
2. *Legislative control by the government (state)*
3. *Novelty production in academia*

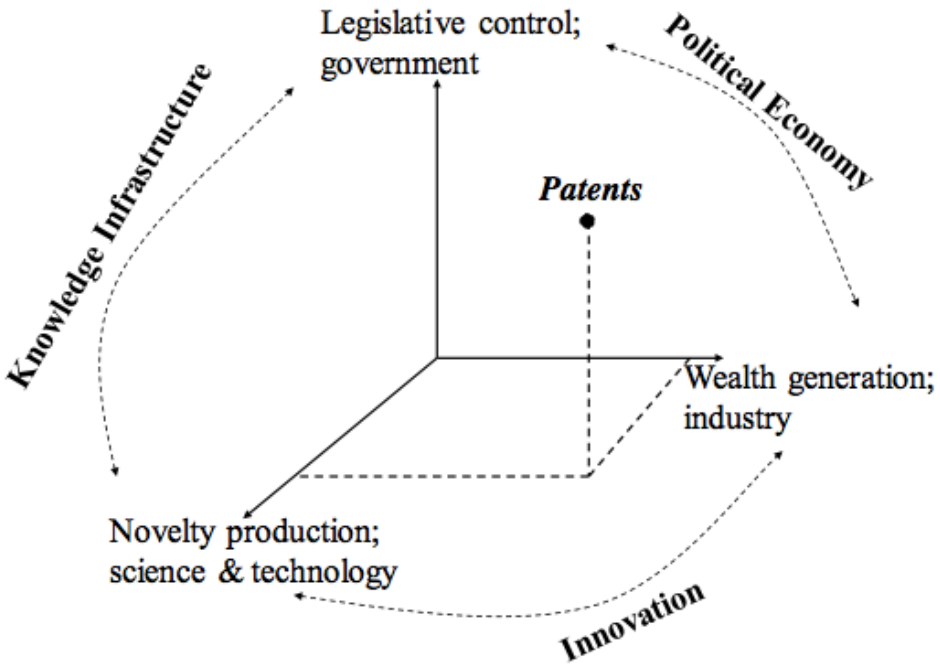

Figure 2.1.2.c Patents as events in the three-dimensional space of Triple Helix interactions (Etzkowitz, 2003)

2.1.3 OPEN INNOVATION PARADIGM

The Norwegian biomarine innovation platforms are constructed by policies to facilitate transfer of knowledge and technology within the actors involved, thus opening the organisational R&D strategies of involved industrial actors. Contrary to the classic model of innovation in an organisation, where internal research and protection by secrecy and isolation generates the new product development (NPD) of the organisation, open innovation suggest a cooperative approach to research and development.

> *"Open Innovation is the use of purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for external use of innovation, respectively. Open Innovation is a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their technology." (West et al., 2006)*

The founder of the concept "Open innovation", Henry Chesbrough, explains the classic business innovation model in organisations as a closed vertical funnel (Figure 2.3.1). Internal ideas and research enter the funnel, but only a few of these efforts make it to the market.

Opening the funnel, metaphorically structured as a "semi-permeable" membrane, to external organisations allow technology- and knowledge transfer to utilize the potential of unsuccessful ideas or research projects (Figure 2.3.1).

Knowledge can be internalised as "spin-ins" from external research projects by technology transfer or joint ventures. Also, unutilized internal knowledge can be transferred to benefit external business development projects as "spin-offs". Chesbrough (2003) summarizes the ideology rhetorically; "*Not all the smart people work for you"*

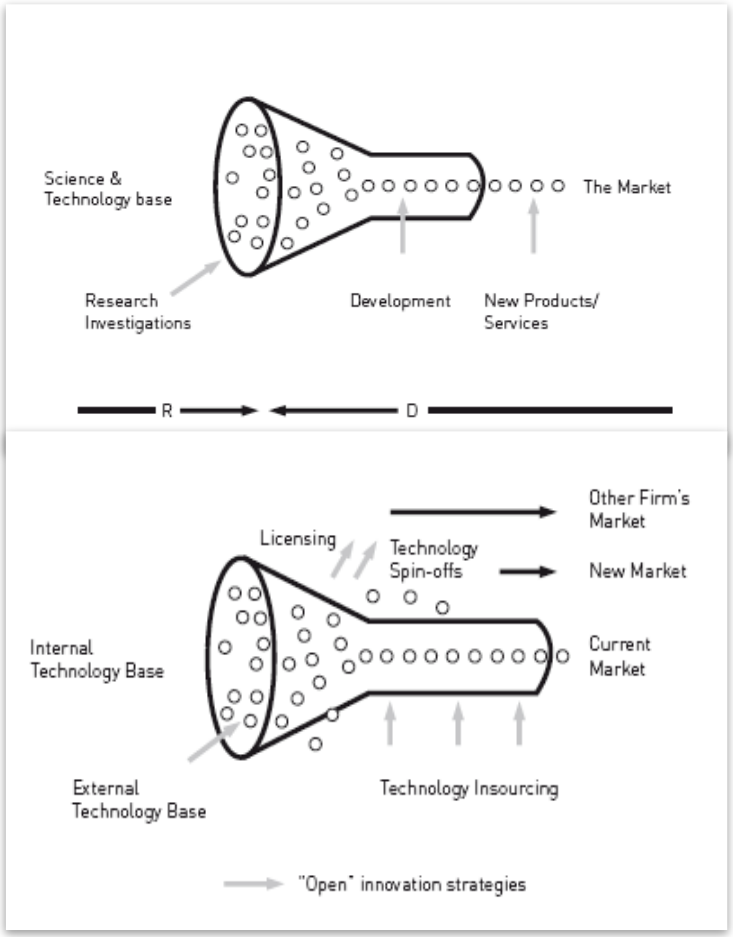

Figure 2.1.3 Closed (top) and Open (bottom) *"funnels"* of innovation strategies (West et al., 2006)

Such a model and the technology transfer need regulation by I.P. agreements to protect the commercial incentive and award the progression of the research by return on investment.

Closed Innovation Principles	Open Innovation Principles
The smart people in the field work for us.	Not all the smart people in the field work for us. We need to work with smart people inside and outside the company.
To profit from R&D, we must discover it, develop it, and ship it ourselves.	External R&D can create significant value: internal R&D is needed to claim some portion of that value.
If we discover it ourselves, we will get it to the market first.	We don't have to originate the research to profit from it.
If we create the most and the best ideas in the industry, we will win.	If we make the best use of internal and external ideas, we will win.
We should control our IP, so that our competitors don't profit from our ideas.	We should profit from others' use of our IP, and we should buy others' IP whenever it advances our business model.

Table 2.1.3: Comparison of the Closed- and Open innovation principles (openinnovation.eu)

The concepts of open source innovation and open innovation share common principles of cooperation and knowledge transfer, but differ conceptually in IP protection of research results and research investment incentives. Open innovation value IP as a vector of cooperation and knowledge capital across organisations, whereas knowledge in open source innovation are distributed more freely among the actors, without capital value. Open innovation can thus be seen as a business model even when the organisation do not benefit technologically from the cooperation.

2.1.4 INDICATORS OF INNOVATION SYSTEMS PERFORMANCE

When innovation is perceived as complex systems of networks, cooperation and knowledge production and industrial application, fully measuring innovation performance by all aspects of the system is difficult. At the firm level, successful R&D investments lead to innovation and productivity growth of the firm, which can

be assessed financially. At regional and national levels too, innovation systems can be analysed financially as contributors to the economy. Innovation systems are however not linear models of financial investments and returns, and their performance should thus take into account more aspects of knowledge production.

2.2 COMMONS AND INTELLECTUAL COMMODITIES

2.2.1 BIOLOGICAL AND INTELLECTUAL COMMONS

Ecologist Garret Hardin (1968) explores a social dilemma, and develop the economic theory "*Tragedy of the Commons",* in which individuals, acting independently and by rational choice according to their own interest, behave contradictory to the whole group's long term best interests by over-exploiting a *common* resource. Thomas Heller (Heller and Eisenberg, 1998, Heller, 1998) extends and flips the theory to a tragedy of the "*anticommons*". Contrary to Hardins tradegy, this theory presents a coordination failure between several rights-holders to a resource, where actors prevent each other's exploitation of a resource by protection rights. The outcome will not benefit the collective utilisation of the resource. Heller highlights patent thicketing in biomedical research and innovation as one of the most exposed systems for such a tragedy.

Where there is theoretical tragedy, there is also a comedy. *"Comedy of the commons"* describes a more utopic system, where knowledge and content is transferred within the system for the good of all the actors exploiting a resource. Together, these theories all depend on economic scarcity of the resource, property conventions, resource management policy and organisation of the actors (Heller, 2013, Buchanan and Yoon, 2000, Hardin, 2011).

	Private ownership	Common ownership
Bad outcome/tragedy	***Tragedy of the anticommons***	***Tragedy of the commons***
Good outcome/comedy	***Successful capitalism***	***Comedy of the commons***

Table 3.1. The tragedies and comedies of the Commons

In Norway there is a strong tradition of publicly funded research be publicly available through academic journals and communicated within the innovation systems. These traditions are under pressure from an increasing expectation of commercialization of research results.

The Convention on Biological Diversity (CBD) was ratified in 1995, as a follow up to UNCED. Its objectives are *"the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding"*. It recognizes (Article 3) that States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction (FAO Fisheries and Aquaculture, internet).

As an adoptation of the CBD to the Norwegian seas, the "Marine Resources Act 3" was implemented by the Parliament of Norway in 2008. It states in section 2: "Wild living marine resources belong to Norwegian society as a whole", coding for common ownership of marine genetic resources. Furthermore, in 2009, "The Nature Diversity Act" was adopted by the Parliament. It states that exploitation of genetic material "from nature" is a common right of the citizens of Norway. These acts represent the basic legal framework for exploitation of marine resources, administrated by the Norwegian directorate of fisheries and aquaculture. It is important to distinguish between the resource and information about the exploitation and application of a resource. In the marine biotechnological innovation sectors, however, they tend to interfere due to national commercial innovation policy (Scott, 1998, Walsh et al., 2007).

2.2.2 *Intellectual property*

> *"If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of everyone.*"
> - Thomas Jefferson

World Intellectual Property Organisation defines IP as creations of the mind: inventions; literary and artistic works; and symbols, names and images used in commerce. Intellectual property is divided into two categories:

- *Industrial Property includes patents for inventions, trademarks, industrial designs and geographical indications.*
- *Copyright covers literary works (such as novels, poems and plays), films, music, artistic works (e.g., drawings, paintings, photographs and sculptures) and architectural design. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and broadcasters in their radio and television programs.* (WIPO.org)

In marine biotech industries, important IP will include discoveries of a biological compounds' industrial application, gene expressions, gene marker recognition, processing technology, synthesis of organic material and more.

2.2.3 INTELLECTUAL PROPERTY RIGHTS

To protect an IP during an innovation project of commercialising the creation of the mind, and to strengthen the incentive of investing in the IP to increase returns in a monopoly situation, IPR can be given to the person or organisation responsible for the creation. It is a legal framework regulating who can utilise the IP.

2.2.3.1 Patents

Within the biological sciences, patents are the dominating type of intellectual property right(Zucker et al., 2002, Adler, 1984), although not in aquaculture genetics by 2007 (Olesen et al., 2007). Patents are a time limited (normally 20 years) exclusive right of the patent holder to decide who could use the patented idea, -and *who cannot*. For an idea to be eligible for a patent, it must be novel, significantly inventive (non-obvious, even for experts) and of technical character with a clear industrial application; a product, a method of production or an application of a component/. Publication of the research results/idea, through scientific journals or more informal publication can therefore prevent patent granting. When filing for a patent the patent holder must however publicly disclose the idea/discovery to be granted the rights. This is to ensure both knowledge transfer and commercial protection. Appendix 3 show EPOs 11 steps of the patent process.

Patent law has however an important limitation: It only creates incentives for research where results can be traded in a market for monopoly price. The core of the system is that those who invest in the invention will receive financial gains from investment by having temporary monopoly (Greenhalgh, 2010). In publicly funded R&D projects where this super-profit does not accrue to the universities or other public organisations, the question of distribution of these earnings arises (Andrews et al., 2006).

When public innovation leads to an invention, there is the opportunity to lay out the invention in the patent to everyone's free use. The IPR ensures public access to the invention, and it might as well have just been published. Alternatively, the patent granted or sold to private and they can develop the invention into a marketable product. Figure 3.3.2 illustrates various licencing options of IPR.

2.2.3.2 Other relevant knowledge protection mechanisms

2.2.3.2.1 Trade secrets

Trade secrets are industry-specific valuable knowledge of a company, which the company has actively prevented publishing in the public domain. For many companies, there is substantial value in these rights. Trade secrets can cover a wide range of information that is important for the competitiveness of the firm, such as specified economic results of companies, purchasing agreements, marketing plans, insight to customer relationships, corporate strategic plans, information about on-going contract negotiations. An important factor to protect trade secrets, are agreements with staff and involved actors inside the organisation. Trade secret law varies internationally. In Norway, infringement of trade secrets are subject to the General civil penal code and the Marketing control act.

Knowledge protection through trade secrets has the obvious advantage of secrecy, keeping the knowledge from competitors. It is also not time limited as long as it is kept a secret. However, trade secrets do not give exclusive rights to knowledge if a competitor produces the same knowledge. Furthermore, trade secret law varies internationally and does not ensure protection across national borders. Enforcement of confidentiality of the rights is therefore difficult and highly uncertain.

2.2.3.2.2 Material Transfer Agreements (MTA)

MTA are agreements regulating transfer of material of research between two organisations. The recipient can utilise the material in its internal research. To protect the results, the agreement should include rights to the material of both parts. MTAs are in biotechnology most frequently used when transferring biological material and derivates thereof between academia for industry. Level of protection by MTA is low, but the agreement is not as comprehensive as licencing of IPR.

2.2.3.2.3 Technological/biological protection

Technological protection can prevent competitors from accessing and repeating the innovative step of a biological organism. In aquaculture breeding, biological protection is the most common protection strategy (Olesen et al., 2007), as continuous upgrading of the genetic material will at least keep competitors that utilise the innovation one generation behind.

2.2.3.2.4 Informal "Know-how"

"Know-How" is undocumented information that only one person or organisation knows, and is the most primitive yet highly popular protection mechanism. Without the knowhow, it may be difficult or unsuccessful for others to utilise the idea. Know-how may be commercially valuable when it is included in licensing agreements. Truly valuable know-how, however, is a rarity. There is no way to record it, and it can be difficult to prove theft.

2.2.3.3 Licencing options

One or more licensees can lease an IP from the IP-holder for commercial utilisation. Licensor will benefit by economic compensation of the licence and do not need to invest more capital to commercialise the IP. The licensee will benefit by direct access to knowledge, without investing and waiting for the research process (Greenhalgh, 2010). A licencing agreement can apply to technology, product, trademark, design, patent and knowledge. The right is usually given for a geographically limited market, an industry, an application or a combination of these. Specific license terms are negotiated in a time-demanding and complex process. Exclusiveness of utilisation and economic compensation are highly important factors, and basis of conflict. The license is a binding legal document, so it is crucial for an IP holder to involve a patent attorney or other legal counsel in the process. In the Norwegian innovation systems,

the TTOs are mostly responsible for this facilitation. Both licensor and licensees can however legally enforce the protection of the IP after such licencing. IPR can also be fully transferred from inventor to commercialising actor by an IP transaction at a fixed price.

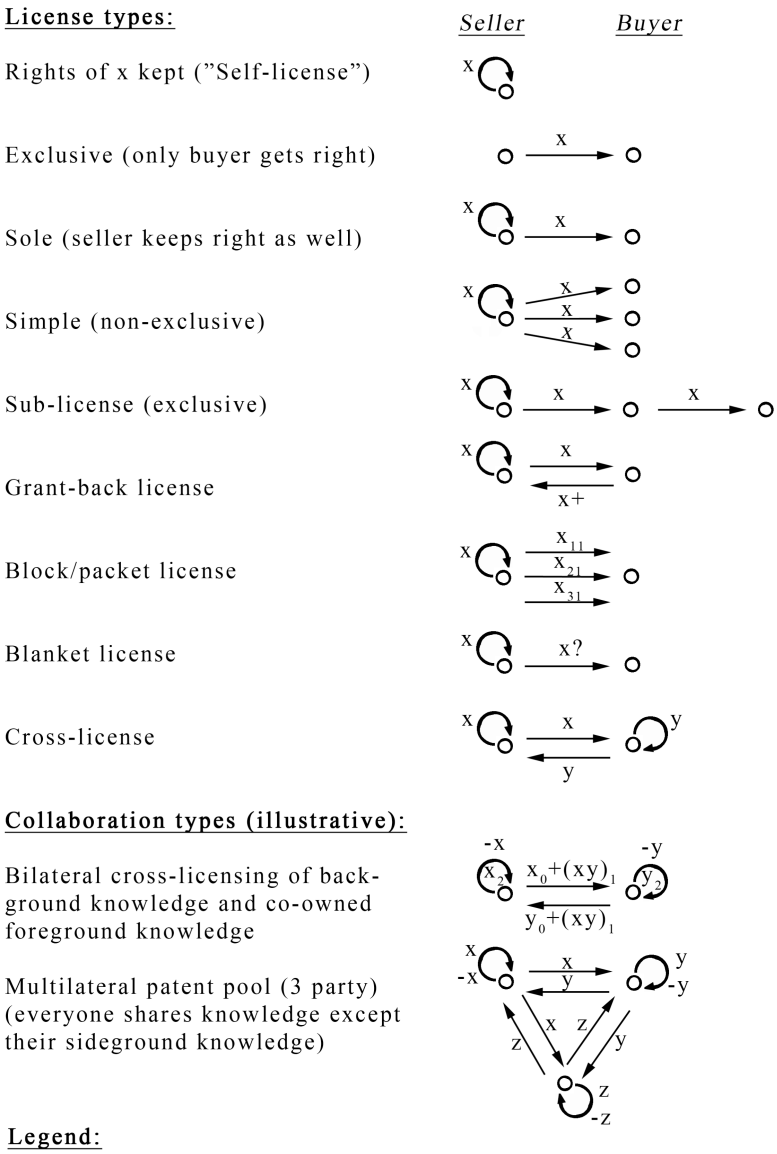

Figure 2.2.3.2: Licencing options of IPR in open collaborative innovation (Granstrand, 2011)

2.3 MODERN INSTITUTIONAL THEORY

Several social trends and questions came to light during the data collection and analysis of this study. In order to explore the social relationships in innovation systems more thoroughly and better discuss the responses of the data collection, paradigms of neo-institutional theory is included in the conceptual framework. National innovation systems need policies and management to support research and its application in industry. How the actors adopt the framework of these policies in their organisations and behaviour is thus important to study when assessing the performance of the system.

Scott (2008) summarizes and extends previous institutional theories presented by the early "new-institutionalists" (Powell & Dimaggio, Meyer & Rowan etc.) and defines institutional theory as cultural cognitive, normative and regulative structures and activities that provide stability and meaning to social relationships and situations. He further defines three theoretical pillars (Table 2.3.1 – 2.3.2; regulative, normative and cultural-cognitive.

- ***The regulative pillar*** is based on jurisdictions, regulatory policies and principles that include corporate governance.
- ***The normative pillar*** is based on sociology and includes norms, values and roles. From a normative perspective, values in defining an ideal standard of behavioural patterns evaluated against, whereas norms define what the ideal behaviour standards can be achieved.
- ***The cultural-cognitive pillar*** is dominated by the social elements that are taken for granted, and that is culturally accepted.

The pillars are correlated as they contribute to each others' construction. Together, they give insight into the three fundamental institutions that are found in any society. Their basis of legitimacy in an environment and the society as a whole is important to emphasise in this sense. Scott defines legitimacy as *"a commodity not to be possessed or exchanged but a condition reflecting cultural alignment, normative support, or consonance with relevant rules or laws"* (Scott 2008: 45).

	Regulative	*Normative*	*Cultural-Cognitive*
Basis of compliance	Expedience	Social obligation	Taken-for-grantedness Shared understanding
Basis of order	Regulative rules	Binding expectations	Constitutive schema
Mechanisms	Coercive	Normative	Mimetic
Logic	Instrumentality	Appropriateness	Orthodoxy
Indicators	Rules Laws Sanctions	Certification Accreditation	Common beliefs Shared logics of action Isomorphism
Affect	Fear Guilt/ Innocence	Shame/Honor	Certainty/Confusion
Basis of legitimacy	Legally sanctioned	Morally governed	Comprehensible Recognizable Culturally supported

Table 2.3.1 Three Pillars of Institutions (Scott 2008)

Regulative	*Normative*	*Cultural-cognitive*
Norwegian patent law: (Patentloven, Patentstyreloven)	Innovation paths history	Public opinion on IPR
WIPO / EPO	University-Industrial Axis	Commons
Norwegian Patent Agency	TTO	Ethical concerns
Marine Resources Act	Existing IP practice	Public opinion on industry
Aquaculture Act	Transaction costs	Sustainability
Biodiversity Act	Geography	
TRIPS	Industry composition	
CBD	Competition	
Nagoya Protocol	R&D Funding	
Best practice report	Clusters / Networks	
	National R&D Strategies	

Table 2.3.2 Institutional pillars of IPR management in Norwegian biomarine innovation

2.3.1 ISOMORPHISMS

DiMaggio and Powell (1983) assume that organizations are becoming more alike to each other in the context of their surroundings, defined as *institutional isomorphism*. Through regulative, mimetic and normative processes, organisations tend to be more alike even if the isomorphism is rational, strategic or effective. Regulative isomorphism implies that governments set requirements for the organization; mimetic isomorphism implies that organizations tend to imitate others (more or less successful) organizations; and normative isomorphism pointing to the professions converging influence on organizations (Dimaggio and Powell, 1983, DiMaggio, 1997). Furthermore, Meyer and Rowan (1977) argue that organizations are becoming more and more alike because they adapt to the requirements of formal organising the institutional environment. All though closely linked, normative isomorphism should not be mixed with normative- or professional legitimacy, which are legitimacies conferred by all actors of society and categorically professional endorsement,

respectively.

2.3.2 *Path dependency and institutional imprinting*

Path dependency, and closely related *institutional imprinting*, describes how the historical roots of organisations shape its development, particularly within established rules and mind-sets that govern the identity and the appropriate action (Colyvas and Powell, 2006). By following these rules, organisations increase both the stability and predictability of development. Principally, the theory evolves around organisational memory of positive feedback from previous behaviour leading to increased returns (Scott, 2008). This historical perspective on organisations have been suggested to constitute a fourth supplementary "institutional pillar" (Section 2.3) (Scott, 2008).

3 RESEARCH DESIGN AND APPROACH

Previously presented theory indicates innovation- and IPR policy as being key determinants of R&D and innovation management in organisations (Carayannis and Alexander, 1999, Hughes, 1988, West et al., 2006), and thus significant to economic development (Mansfield, 1990). Innovation should furthermore be observed as a system (Isaksen and Karlsen, 2010, Katz, 2006). Within the system it is necessary to explore the social interactions and perceptions among core actors to understand the actual construction of the system and the role of a particular element (IPR in this study). Qualitative research is of specific relevance to the study of social relations and behaviour.

Despite recent controversies and political awareness on the subject of IP on biological resources, there has been little research on the role of IP and IPR in bio-marine innovation systems. The novel nature of this study suggests an abductive exploratory approach, without biased topic preconceptions, which will be generating hypotheses by empirical findings rather than testing predetermined hypotheses (Silverman, 2010).

3.1 RESEARCH DESIGN

At initiation of the project, several explorative, unstructured discussions and interviews with actors of the marine biotechnological industry and academic scientists of relevant prior research were conducted to point out relevant topics for the study. Here, NOFIMA allowed access to data from a survey/questionnaire conducted in 2011 on experiences from-, and attitudes to intellectual property among actors of publicly funded Norwegian aquaculture biotechnological innovation platforms related to aquaculture (FUGE (Functional Genomics) and Havbruk (Aquaculture) programs of the Research Council of Norway. The findings from the survey generated topics for further elaboration to better understand the phenomena in the innovation systems related to marine genetic resources. As IPR management on genetic resources in the aquaculture industry have gained much attention, a case study of a more experienced platform was included to the study for comparison and contrasting the role of IPR across institutional environments, but with similar policy- and regulatory regimes. Section 3.2-3.3 will present the two innovation systems in the study. Patterns in the data will contribute to an overall understanding of determinants of IPR management.

These determinants will be in the search light throughout the data collection and analysis.

	Part 1: Aquaculture Research Programs HAVBRUK & FUGE	**Part 2: Marine biotechnology innovation system**
Means of data collection	Survey responses (Qualitative/Quantitative)	Case study, semi-structured depth interviews (Qualitative)
Data material	Second-hand data	First-hand data collected
Aim of study	Examine how IPR and regulation of access to- and utilisation of marine and aquaculture genetic resources may contribute to innovation and development of new and improved products in aquaculture.	Explore how a biomarine innovation platform (concertium) handles IPR issues arising from publicly funded R&D-activity based on utilisation of marine genetic resources.
Aim of full study	Explore the factors that are dominating in IPR management strategies in Norwegian marine biotechnological innovation systems – and what are their effects on the performance of the system.	
Participating respondents/informants	Project leaders of research programs (representing both public and private sector)	Researchers, Administrators, Facilitators and Legal advisor (representing both public and private sector)
Year of data collection:	2011	2013
Analysis	Quantitative / Qualitative Citation coding	Qualitative: Citations coding, abductive, (discourse analysis)
Related innovation systems	Sectoral, international,	Regional, sectoral

	national, regional, local	
Genetic organisms in field of research/innovation	Atlantic salmon, marine fish, virus strains, disease vectors	Possibly all marine biodiversity
Possible protections	Gene marker, process, organism (virus), trademark	Process, novel bioactive compound, gene expression,

Table 3.1 Presentation of the innovation systems in the study

3.2 AQUACULTURE SURVEY: EXPERIENCES FROM AND ATTITUDES TO INTELLECTUAL PROPERTY IN TWO PUBLICLY FUNDED RESEARCH PROGRAMS.

A web-based survey (Appendix 1) was sent to project leaders funded by the FUGE technology platform or HAVBRUK related to aquaculture. 55 project leaders were invited to answer the survey, representing Universities, governmental funded public research institutions, private research institutions and researchers in the industry. NOFIMA designed the survey, chose respondents and collected the responses. The design will thus not be presented in this thesis. I will analyse the results as second hand data, and comment on the research design in section 3.5-3.7.

3.3 CASE STUDY: MARINE BIOTECHNOLOGY INNOVATION CONSORTIUM

To further investigate the complex rationales of IPR management among core actors of the biotechnological industry, a depth interviews was conducted in a knowledge based innovation consortium in a specific industry. The case was chosen on basis of several criteria: Norwegian, biotechnological innovation with marine genetic resources and thus similar legal sphere, emphasis of IPR and composition of representatives (University researchers, TTO, knowledge bank, analysis platform and industry partners).

Within qualitative methods the case study approach has been chosen because it enables one to understand the dynamics within relevant settings. Moreover it attempts to examine a contemporary phenomenon in its real-life context.

The selection of case is of great importance when using this research method. A single case study is analysed; a Norwegian marine based biotechnology innovation

consortium with both public and private actors. To extend the perspective on the aquaculture industry from the results of the initial survey data, this case was chosen to compared and contrast the institutional similarities and differences between the industries, and how the innovation systems have adapted to them. This approach refers to the 'relevant case', yet significantly different for other perspectives. In the present research the case has been identified to be typical: it examines in detail a single phenomenon (IPR management), which is considered to be particularly relevant for other comparable marine biotechnological industries. Various selection criteria have been used to ensure this relevance: marine based biotechnological R&D activity, funding, number of researchers, public and private actors, patent activities (number of patents per year, number of protected inventions, patent strategy; more than aquaculture and thus interesting to compare and contrast), organizational structure dedicated to patent activities (relationships with other departments, TTO etc.). The selected innovation platform provides a better understanding of the research question of the study, as the selected industry sector is in a globalized setting, has more experience of- and emphasis on IPR management.

When designing the interview guide, broad themes were introduced to determine the dimensions of IPR management the informants emphasised mostly. Conversation structure was planned to be loose, in order to follow up interesting questions during the interviews.

4.3.1 SELECTING INFORMANTS AND EXECUTION OF INTERVIEWS

Interviews were conducted with key informants involved in strategic development, novel research and intellectual property management. Secondary data enabled the completion of primary data. Two main periods must be distinguished in data collection. The informants were selected by communication- and recommendations by independent- and core actors. Actors recommended most frequently were further assessed by criteria; without ownership or commercial interest in industrial partners (assessed by public database; The Brønnøysund registry – brreg.no), lead positions in consortium representing different contributing institutions. Gender composition of the respondents was also considered, with a final ratio of males and females (4:2 respectively). They were invited by e-mail and phone to attend the interview in their offices. Due to the complexity of the study and expected full schedule of informants,

a brief review of the aim of study was handed out before the interview (Appendix 3a), and estimated duration of the interviews was to 45 minutes. Most of the interviews were however extended beyond the estimated duration.

General perceptions on IP and access to genetic resources will give great contribution to the overall project. At this stage it was important to avoid the bias of actively "looking for" similar findings from the respondents. (Silverman 2005).

3.4 Analysis

Due to few respondents and varying response counts on several questions, survey results from the aquaculture research projects could not be significantly analysed by classic statistical methods. A triangulation of methods was initially planned to ensure reliability and validity of the qualitative findings. Both studies will however be discussed combined to reveal behavioural patterns and reasoning in the institutional environments. Notes of comparisons and hypotheses during the whole research process will be added to the data collected and analysed accordingly.

Case study recordings and interview notes are repeatedly analysed to construct code of the most important topics for discussion. To grasp the full extent of the case study, informants from very different positions in the system were selected. The interviews differed thus accordingly, and classic qualitative analysis methodology by frequency coding of transcripts was not applicable. The structure of analysis will include elements from discourse analysis. There are variations of approaching this analysis framework, across scientific disciplines and topic of research. Discourse analysis, however, involves studying human texts, actions and symbols, and how they are socially constituted by habits and conventions, which are perceived as "natural" to the actors. The guiding principle is to combine analyses of expressions, written work and communication with analysis of the culture and society.

3.5 Validity and reliability

This paper relies on one survey and one compared case study. The validity may thus be limited for the aquaculture industry as a whole. However, the data collected in this research will form some perspectives on *de facto* juridical application, social constructions and behaviour, and institutional mechanisms. The aim of the project is

merely to investigate relevant constructed mechanisms within the institutional setting of the Norwegian aquaculture.

Partly or fully, some of the projects studied were initiated by public funding. The informants were considered to be insightful and open for the survey and interviews. By communicating with the responder as a subject and keeping to a semi-structured interview guide based on industry knowledge and topics within the theoretical framework of the thesis, it is considered likely the informants are reliable sources of information. The respondents also received some key aspects on the topic prior to the interviews to prepare the data collection. To ensure reliability of communication during the interviews, a summary and key information was discussed at the end of each session for correction and additional information.

3.6 Ethical considerations

The study will use standard procedures in case study open interview methods, as suggested by Silverman (2010). All persons interviewed in the case study were provided limited details of project prior to the interviews. The informants will have the option of remaining anonymous in any reports or studies made public by the project participant. Any private or restricted data collected within the framework of the study will be collected with the explicit consent of informants.

3.7 Criticism and limitations of the design

***Aquaculture survey**:*

Number of survey respondents and the participation among the invited actors were limited. The data could therefore not be significantly analysed in statistical testing. Hence, analysis did not adhere to the research design. However, the observed trends gave insight and were supportive to the study. Explanatory answers to open ended questions were also included to the qualitative data of the study.

Case Study:

Time limitation: My stay for conducting the interviews was short and my objective of attracting informant participation by effectiveness of the interview may have contributed to reduced data collection. Extensive preparation, recording, coding and progressive analysis of data implied that the time for conducting the interviews was

too short. Most interviews were considerably longer than scheduled, and the conversation dynamics of some interviews was hampered by time limitation, thus affecting validity.

Information bias: Information note to interviews may have been "too informative". Some of the informants responded very similar, even from very different positions in the system. As the innovation system is regional, sectoral, and rather small, informant interaction prior to the interviews was very possible. This may have been a contributing factor to the similarities in the responses.

Full study:

The two biomarine industries of study differed more than expected when designing the research. Initially, the marine bioprospecting case study was included to contrast the IPR management in the aquaculture industry. Data collection and analysis was challenging in a comparative form as the two studies also differed substantially in design. This thesis will thus present trends and patterns that came to light. The reliability of transfer of findings between the industries should be considered hypothetical and basis of further research.

4 FINDINGS AND ANALYSIS

4.1 AQUACULTURE SURVEY: ATTITUDES AND EXPERIENCES OF IPR

4.1.1 RESPONSE OVERVIEW

Web survey responses from (25 out of 55) project leaders were received, representing 34 projects (some respondents were project leaders on several projects). The 25 project leaders represented both non-profit and profit organisations, private and public research institutions, and the institutions were both internationally and national owned. Most of the funded projects, and thus interviewees, were non-profit organisations, representing academia and public research institutions. Some were working primarily with research, while others had commercial goals. 48 % of the respondents answered that their research was financed by industry and public in combination. 32 % answered mainly industry, while 20 % were financed by public funds. Most of the respondents were working with animal health/disease and genetics, while a few were working within nutrition, pharmacy, technology and engineering.

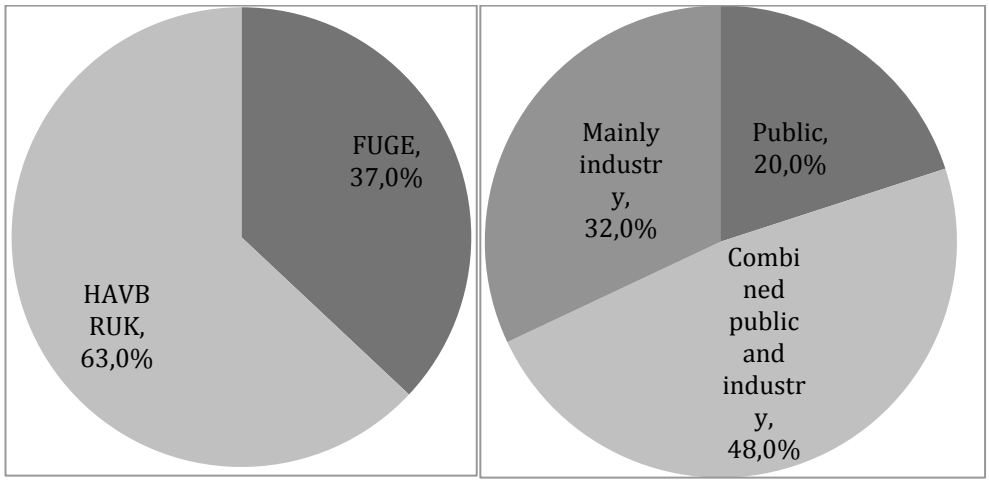

Figure 4.1.1a Presentation of the respondents; Research program and institutions research funding

4.1.2 PROTECTION OF FINDINGS

40 % of the respondents had plans of securing IPR of findings in their projects e.g. through patenting, when they applied for funding.

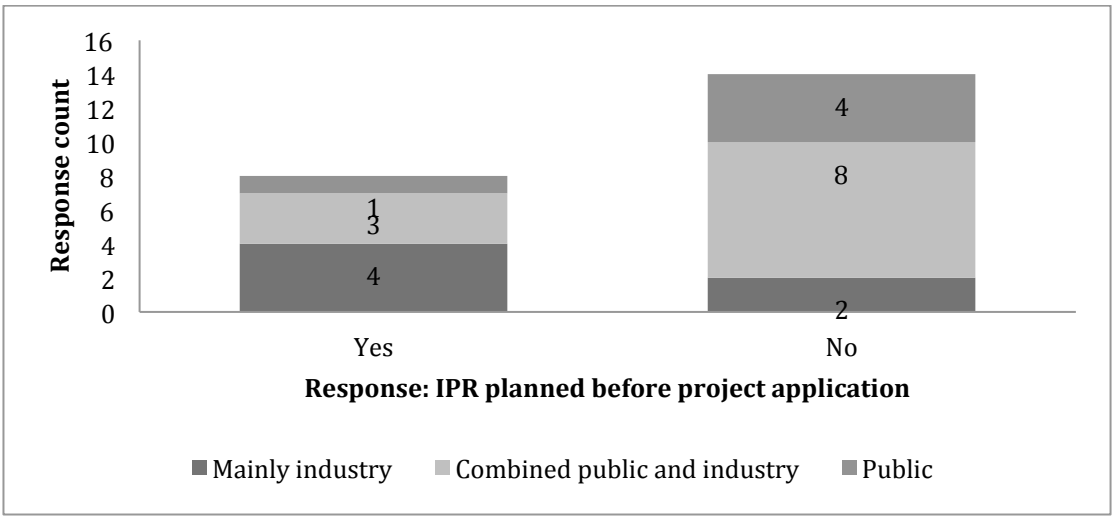

Figure 4.1.2.a IPR planned before research project funding application, institution funding biased.

During or after the project was finished 30 % said that there was a need for protecting the new innovations through some type of IPR system. They intended to protect:

Product	**70%**
Gene, Marker, Organism	**70%**
Process	**30%**
Method	**50%**

The respondents who answered yes to whether they intended to protect their findings, were also asked to answer what type of protection they would use.

- *Only protection is publishing ahead of others -- agreements about that may be necessary some times, when a new method is involved*
- *Maybe protection of candidate vaccines - if any.*
- *If working with universities/institutes or commercial companies agreements have to be signed specifying ownership to IPR. Background has to be stated, will be unique for each "party", foreground might be shared. We always want the rights to commercial usage of results and IPR*
- *Should always be but difficult to manage*
- *New disease agent identified*

The respondents were asked to rank from 1st to 4th choice five different strategies regarding the legal arrangements in addition to “I would rather publish” and “I would

rather keep it secret". The choices were scaled as follows: 4 points for a 1st choice, 3 points for a 2nd choice and so on. Patents got the highest rating among legal arrangements of IPR. Publishing came second, followed by contracts, however the difference between them was small. Mainly industrial funded projects tended prioritised patents, whereas public funded projects preferred publishing the results. Technological/biological method and keeping it secret was the fourth and fifth choice respectively, responded only by combined and industry funded project leaders. Trade mark/service mark and copyright were ranked on a sixth and seventh place respectively.

4.1.3 EVALUATION OF PATENTS

60% of the respondents who did not apply for a patent during the research project expressed that the main reason for not filing a patent was that the findings were not patentable. 20% of the respondents considered their research results as open/free access, and did therefore not file a patent. Further 20% of the respondents not filing a patent, replied their main reason to be demanding process of patent filing.

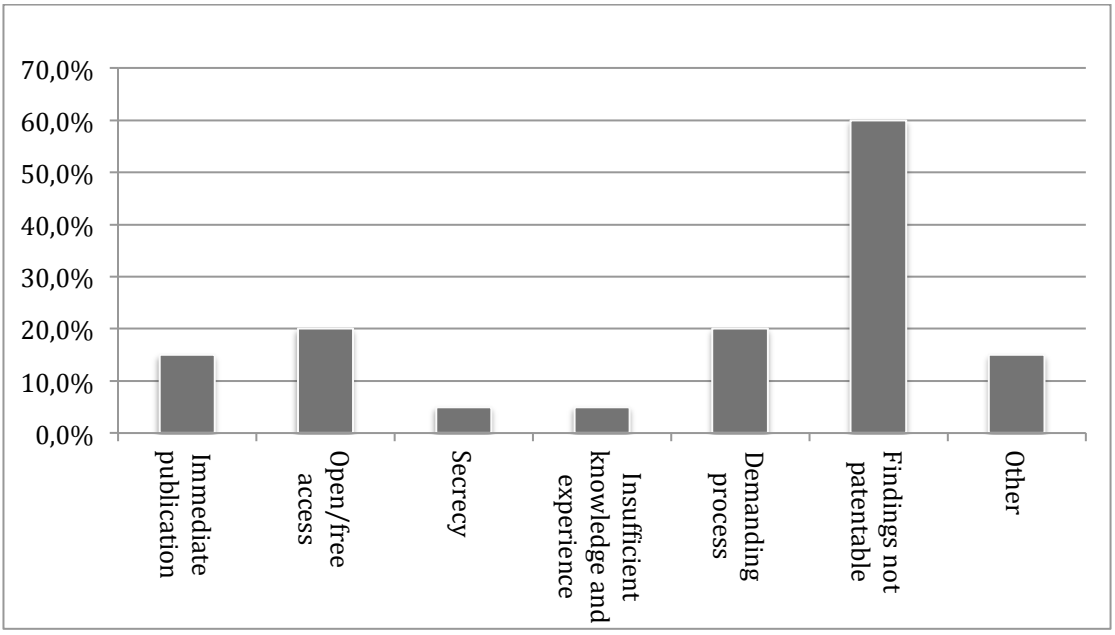

Figure 4.1.3 Main reasons for not applying for a patent

4.1.4 EXPERIENCE OF IPR

54 % of the respondents had experiences with IPR practice in earlier projects, mostly with patent applications, and one with trademarks.

Their experience varied widely, some researchers had both positive and negative experiences with patent application, here are some quotations:

- *cost and time consuming process*

- *long time to wait before conclusion*

For some, findings were rarely patented, and they rather chose to regulate IPR in agreements and clauses with cooperative universities and research institutes to postpone publishing of knowledge for a reasonably amount of time.

One industry partner said that they only did collaborative research with universities or research institutes as long as the new knowledge was kept exclusive and as an intellectual property. Another said that he/she had both experience with patent application, and with patents from competitors stopping them from development of new products. The same researcher responded that their company were willing to spend money on research when they knew that IPR would be secured, and it was not so interesting to spend money if a cooperating research institute/university refused to license the findings, or wanted to publish immediately.

Yet another researcher answered that their experience was generally negative, and that the aquaculture industry has been too small or immature to handle the patent issue. One also responded that he/she tried to publish to prevent others from patenting.

4.1.5 IPRS EFFECT ON RESEARCH

46 % of the respondents had experience from encountering others' IPR which had affected their research.

Collected quotes:

- *Competing firm that hold a very broad patent hindering development of the vaccine against one specific disease, and the competitors use of their own patents.*
- *Protest against a patent/patent application that they thought was not valid and would influence the use of their products or services.*
- *Industry partner that wanted to apply for a patent, postponing the researcher's publishing of results for a couple of years.*

- *Competed yearly with other industries to have first and exclusive use of the same knowledge and product.*

The respondents felt that a strict regulation of IPR influences research. 25 % expressed that it had no influence, 33 % expressed that it promoted research and 42 % expressed that it hampered further research (Figure 4.1.5). Some of the respondents commented that some patents hamper research (i.e. if the patent blocks the development of a certain product there is no point in doing research), but on the other side, patents will stimulate to do research by the patent holder. Research is not "*per se"* stopped by patents, but it will influence who is interested in it.

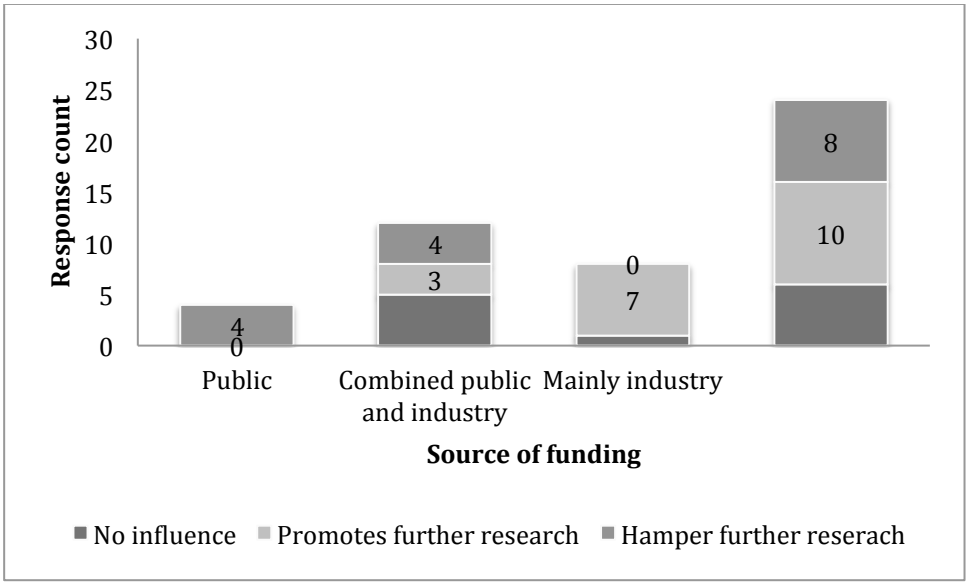

Figure 4.1.5 Attitudes to strict IPRs influence on research, funding biased.

4.2 MARINE BIOTECHNOLOGICAL CASE STUDY

Proceeding from the findings of the questionnaire, depth interviews were carried out of 6 representative actors from a marine bioprospecting innovation system regarded to have more experience of IPR management. The 6 informants are core actors, representing of all stages of the innovation process and have experience from most stages of innovation diffusion, from both academia and industry. Their input will thus present different views, experience and opinions about IPR and establish a wide platform to discuss the research question of this paper.

This section will present key findings from both expected and spontaneous topics. Expected topics were included as "leads" in the interview guide, but due to the

novelty of the research topic, exploratory nature of this paper and its methodology, the conversations were promoted to also investigate spontaneous insight evolving from the context. Repeated "run-throughs" of interview recordings and reading of notes generated hopotheses and brought additional theory to the conceptual framework. The result is presented in codes (appendix 2), or information topic groups, and several quotes were extracted to emphasise the results.

- NN1 is a researcher representative of academia (public funding)
- NN2 is a researcher and project manager of a non-profit research institution (mixed funding
- NN3 is a business developer from Transfer Technology Office (public funded)
- NN4 is a leader and administrator of resource and knowledge bank (public funded)
- NN5 is a administrator of a regional innovation platform, representing state (publicly funded)
- NN6 is an IPR attorney respresenting the interests of commercial actors.

Quotes are outlined in bulleted *italic* form.

4.2.1 Network and alliances

The informants were well aware of formal networks in the innovation system, but some also expressed the structures were not fixed as external activities, shifting of and adaptation to external and internal actors interests and innovation policy caused great dynamics of the system. By the informants' introduction, and further questions of inputs and outputs of their positions, the system was considered as both dynamic and complex (Katz, 2006) in terms of financing, interests, relations and institutions. As the industry is at an experimental stage, most of the funding is however public.

One informant expressed that certain regional industry actors in the system were prioritised when novel information was to be transferred. Limited number of industry actors directly involved in the consortia causes discoveries from research to be channelled directly to a specified actor by its business model. Another informant explained that industrial actors were actively promoting topics of research they needed from academia, which further emphasises a multilateral dynamic network between hybrid organisations of a triple helix system.

4.2.2 FACTORS OF RESEARCH/INNOVATION STRATEGY

Many of the informants expressed that the research strategy of the system is based on research strategy of academic institutions and factors of commercialisation; interest of commercial actors, global positioning of potential IP to existing IP (for prevention of IP-conflicts) and IPR granting framework.

NN1 explain that research policy of the Academia is the main factor for research strategy. Furthermore, "international IP-positioning is important, as publications or patents from similar external research processes can block an IPR-filing. This delimitation of strategy is mostly positive when searching for novel compounds."

NN2, NN4 and NN6 also value global IP-positioning as an important factor of strategy.

4.2.3 INDUSTRY COMPOSITION

Composition of industry actors are highly mixed; from one single researcher to big pharmaceutical producers. Technological infrastructure, legal enforcement- and management of protection were expressed to be limiting factors to successful development. National actors are small and highly specialised in developing a discovery, whereas end markets are big international pharmaceutical corporations capable of carrying the complete process of innovation diffusion and enforcing protection of the IP. The generated knowledge is thus considered among many of the informants to yield only temporary innovative success at a regional and national level. There is currently

4.2.4 EXPERIENCE AND ATTITUDE OF IP

Means of IP:

Overall consensus of patents being the only fully applicable IP for commercialisation was observed in the innovation system. Internally, other means of protection such as MTAs, confidentiality agreements and informal knowhow were used as a necessary precursors of final global disclosure and protection through patent applications.

- *"Yes, patenting is the only applicable means in this industry"*
- *"Highly important in the processes. Patent is cash"*
- *"Patents are good protection of high investment costs. The patent system is however made for products and not processes or progression (services).*

Patents are considered difficult because it is unknown for researchers. IPR agency important"

-

Experience:

Most respondents expressed positive experiences of protecting inventions, particularly patents. Some respondents indicated the application procedure and the legal arrangements to be laborious and time demanding. Prior preparation by IP positioning of research and competence on the patenting procedure and legislation was considered important for filing efficiency.

- *Positive experience. Requires competence and preparation*
- *Only positive! But admits partners in general have the opposite view.*
- *Yes, both positive and negative. Mainly positive, but efficiency important for early publication (as a researcher)*

4.2.5 TECHNOLOGICAL CONSIDERATIONS TO IP-STRATEGY

Lead compounds such as chemical molecules, enzymes and biological applications were considered best discoveries for IP protection. Two informants wanted application of complete organisms (low taxonomy class) to be patentable in order to have sufficient protection height for securing major investments in development of complex innovations. When searching for a licensee for commercialisation, two informants explained commercial actors strategy of shopping for wide-scoped patents that has better chances of innovation success, due to freedom to operate within the scope. Meeting this strategy is considered when deciding for research and IP strategy of findings.

- *"Chemical molecules are preferred for protection, but also biological application."*
- *"Mainly Enzymes + biological application preferred. Enzyme in general is seldom accepted. Must be very specific (species). Bio Application is ok*
- *"Important to have broad application rights. Freedom to operate"*
- *"Substance, structures, synthesis + application."*
- *"Lead compound, high patent, bioprocesses are difficult"*

4.2.6 DURATION OF PATENTS

- *"Timing of patenting and licensing is essential for maximum progress in duration"*

Commercial development, testing and diffusion of products is time demanding in the related end market industries. Patent rights are limited to 20 years after granting. In these years, the right-holder must develop product(s) and gain returns on R&D investments by the monopoly situation given by the patent. When development is long, the industry actor will do as much as possible before the patent application is filed. Several informants were concerned with this component of patent law.

4.2.7 PUBLISHING VS. COMMERCIALISATION

Researchers indicated that commercialisation policy of the innovation system delayed publication of publicly funded research results, even basal research results that could be considered significant to the discovery that could lead to an invention. One was concerned by this dynamics failure of knowledge production, but loyalty to the mission of the consortium – to put the knowledge in regional industries – was considered more important. Commercial actors and the facilitator addressed the opposite concern; Researchers desire (and right) to publish results is a significant obstacle to commercialisation, as complete secrecy is vital prior to disclosure through patents. All respondents commented on this topic, and were aware of the concern, without motivation by the interviewer.

4.2.8 OPENNESS OF THE INNOVATION SYSTEM

Administrating actors said the consortia system was modelled on open innovation and the triple helix paradigm, as IPR was licenced to industrial actors in many ways. None of the informants were aware of inter-licencing of patents between the industry actors. Only MTAs and the standard confidentiality agreement of the consortium were transferred IP when the actors cooperated. One informant claimed "*Joint Ventures are not very applicable to biotechnology, as the research is specific and compound-oriented, and will not benefit two parties with different aims"*.

Reuse of "unsuccessful" IPR:

One respondent commented on a European Union funded innovation platform for marine bioprospecting that had a "black box" (patent pool) of unused patents from the actors within the platform. The other informants had no experience of reuse among

the industrial actors as the IPR and the commercial interest of the actors was too technical oriented and interest in other technology/information for development was "*categoric; yes/no."* Informants that were listed as inventors are handed the right to personally file protection for the invention when neither academia nor industry partners are interested in developing the invention. Two of the informants had kept IPR personally, but the overall perspective from informants was rejection of the inventions commercial potential if there was no interest in the limited system.

5 DISCUSSION

Within the framework of innovation- and institutional theory, I will in this chapter discuss coded findings presented by topic code and specific quotations from the two sets of data collected in the research and propose some further questions relevant to the topic of IPR management and its role in marine biotechnology innovation.

5.1 PERFORMANCE OF INNOVATION PLATFORMS

From the case study, perceptions on innovation systems performance indicators varied greatly. Some perceived the system as a mediator of knowledge resource management, while others perceived the platform solely as a facilitator of commercialisation. However, all informants seemed loyal to the commercial strategy of research within the consortium. The roles and positions of the informants varied and is a strong bias when analysing this topic. It seems as the complexity of institutional forces cause fragmentation of actors' perceptions of the mission and context of their innovation system. They value open knowledge, but accept IPR regimes.

According to the triple helix model, innovation systems performance can be seen through the dynamics of the actors relationships, their contributions and vectors of knowledge exchange (Ranga and Etzkowitz, 2013).

Hence, when discussing IPR, this system appears to function inefficiently as IPR diclosure is delayed by legal arrangements and strategies of commercial progression within the patent period. Dislocation of knowledge is furthermore observed as linear relationships from academia to one specific industry actor, where failure of innovation rejects the invention as commercially viable. Institutional isomorphism occurs when members of organisations progressively act alike, even if their actions and attitudes are not representative of their rationality (Dimaggio and Powell, 1983). The informants' perceptions on patents and prior secrecy, and loyalty to the current IPR management regimes can illustrate evidence of isomorphism in the system.

In the aquaculture survey, more respondents expressed their goal of research as altruistic in the sense of contributing knowledge to the public domain.

5.2 IPR AS CAPITAL

"What can you sell, if you do not have patents?" In the case study, all actors indicated that the actual innovation process in Norway was very short, only from discovery to pre-market testing and the realistic aim of innovation was sale of company or IPR to international industry actors with power to create a product and diffuse the innovation to a market. This response conflict the communication of the innovation system, which aim to support a regional innovation cluster by dynamic technology transfer from publicly funded academia.

In the aquaculture sector, however, most actors are either suppliers of products and services to the aquaculture industry or they use the IPR in their integrated production to supply seafood.

No evidence of patent being an incentive of researchers performance = no researchers claimed the IP of an "unused" patent.

5.3 ARE PATENTS THE SOLUTION?

Empirical evidence from both industries portray many pitfalls of patent law in the innovation system. The main concern is patents hampering of research results publishing, and thus contributions to further research.

Quotes from case study:

- *"US system of 1 year of IP protection post publication (Grace period) should be applied in Norway"*
- *"Researchers withhold publishing of important results, which affect scientific communication (presentations etc.) and education (PhD, other University education)"*
- *"The secrecy and one-directional use is a weakness when the access to resources shall be equal to all"*

Time between IPR agreements and Patent filing prevents publication and further relevant research. Researchers are frustrated with slow IPR agreements in the innovation consortium and thus late patent application. In Norwegian academia, researchers as employees are expected to report a *disclosure of invention* form (DOFI) when their research results may be of commercial value. The information of the disclosure is evaluated by TTOs who usually encourage the researchers not to publish

the results before a commercialisation plan is set. In some countries, like the USA and Japan, the so-called *grace period* is meant to remedy the consequences of prior publishing by inventors, which in turn destroys the novelty requirement for an invention to be eligible for patent granting. Such a grace period specifies a certain period of time (six or twelve months) in which the inventor still can file a patent application, despite the prior disclosure of the invention. As a result, the novelty requirement is undermined and a patent may still be granted, provided that all other requirements for patentability and the formalities are met (Franzoni and Scellato, 2010). The invention can thus be made publicly available right after discovery, and long before commercialisation/IPR strategy is planned. Furthermore, industry actors both within and outside the innovation system can evaluate the invention and suggest several plans for commercialisation before the duration of the grace period. This flips the constraint found in the case study that suggest secrecy is vital before a commercial strategy is planned and legally arranged. Perhaps the limited time of grace period can even promote IPR handling efficiency.

Several countries have variations of similar periods in their IP law, and the EPO is currently evaluating the system in their framework. International variations of such periods will however challenge the protective nature of the system. When applying for a patent for the same invention in different countries and regions simultaneously, the national definitions of the grace period cause difficulty as such a period may be used to obtain a patent in certain countries and regions, but not in others. Furthermore, such a situation lead to a situations where the invention may be used by third parties without restriction, in countries and regions that do not have a grace period (Franzoni and Scellato, 2010).

5.5 Opening the innovation systems

No informants in the bioprospecting case study saw any alternative to patent protection. Two informants expressed that the innovation platform was based on open innovation, but there was little evidence of exchange of IPR. Inventions were rather sought out to a predetermined industry partner, and little evidence of communicating the finding across platforms or publishing. Joint ventures were also expressed to be impossible in the innovation system, as the actors are technically specialised. Furthermore, none of the actors could recall any other type of licencing than

exclusive-, and sole licencing, despite their opinion of innovation openness. The reasoning was perceived by two informants to be an adoptive strategy to biomedical innovation norms and market, thus suggested to be institutionally mimetic.

5.6 LEGITIMACY OF THE IPR SYSTEM

"The strength of an IPR is limited by the IPR-holder capability of defending it"

"University holding patents for licensing is utopic, the resources needed for IPR protection is too great and complex"

Norwegian universities lack the ability of patent administration. Three actors indicated that the patent system was not sufficient protection when universities and TTOs held the IPR and licenced it to the industrial partner. Patent law is moreover experienced by many responding actors of both industries to be too strict, and application procedures too laborious and time demanding. Other IPR options were in both studies believed to be insufficient global protection mechanisms.

"Patents are good protection of high investment costs. The patent system is however made for products and not processes or progression (services). Patents are considered difficult because it is unknown for researchers. IPR agency important"

Researchers have little insight to patent law and

5.7 TRAGEDIES OF THE ANTICOMMONS.

"Researchers withhold publishing of important results, which affect scientific communication (presentations etc.) and education (PhD, other University education)"

"The secrecy and one-directional use is a weakness when the access to resources shall be equal to all"

All internal informants of the case study perceive secrecy of researchers findings until IPR is secured as ethically problematic when the research is mainly publicly funded. The industrial partner, however, finds it problematic that researchers wish to publish their findings as soon as possible and does not have insight to the complexity of the regulatory framework of an innovation process.

In the aquaculture survey, strict regulations of IPR was over-all responded to hamper further research as others IP were experienced to block development of inventions, whereas IP-positioning in the case study of bioprospecting was considered an advantage to narrow the aim of research and make the development process more efficient.

Wide scope of protection is strategically important for many of the respondents of the survey and the informants in case study. *The tragedy of the anticommons* can thus be considered present in these innovation systems. Two important bioinformatics knowledge banks are currently being formed in the two studied industries; (1) Salmon Genome Project, a complete genetic map of the salmon genome for aquaculture genetics industry and (2) MARBANK, a national biobank of samples of a wide range of marine genetic organisms for utilisation in marine biotechnologic industries. When they are fully operational, these systems can be viewed symbolically as seas of limited available resources (knowledge) where the actors are "fishing" for potential IP. Protection by wide scoped patents increases total harvests per IP, but the by-catch, which can be of importance for others, is significant. As patent law is not designed for biotechnology, this practice should be evaluated when designing the banks of bioinformatics.

5.8 ALTERNATIVE FRAMEWORKS FOR KNOWLEDGE TRANSFER MANAGEMENT

5.8.1 OPEN SOURCE FRAMEWORK

Biological science differs from software development and source code. In software, copyright dominates, and the start-up cost for developing software is relatively low compared to biotechnology. An open source framework for inventions from marine biotechnology needs to create similar incentives as those created by patents, taking innovative conditions for the sector particularly into account.

Joly (2007) reviews several open source-based biotechnological projects and the aspects arising of this application. His conclusions suggest a general negative view of open source applicability on innovation on genetic resources, but open source can compliment and sometimes work best as an independent alternative to the innovation paths of proprietary rights incentive.

The informants of the case study did not see any commercial alternative to patents as IP-protection in their field of biotechnology innovation. Joint ventures of innovation was also considered inappropriate due to the fragmented technological strategy of the actors.

6 CONCLUDING REMARKS

Because of the major social changes and increasing institutional expectations, innovation systems meet significant management challenges to knowledge protection and transfer. Fragmented IP management models restrict knowledge production and block the implementation of appropriate protection strategies. IPR can however be perceived as mediators of interorganisational cooperation (Petrusson and Pamp, 2009).

Important factors for IP strategy in the biomarine industries are found to be:

- Patentability (Patent law, IP positioning)
- Scope of patent and thus freedom to operate (refining the specific interest)
- Time of disclosure for progression within the patent period for complex and time demanding innovation processes such as pharmaceuticals/bioprospecting.
- Licensee preferences (scope of patent,
- Contribution of knowledge to the public domain

Banks of marine bioinformatics that are now in development can play an important public role as innovation platforms in the two industries studied. This study suggests the banks IP policy should take into account:

- The difficulties of patenting genetic organisms
- The effect of wide scoped protection
- Implications of granting confidentiality prior to IP filing
- The importance of IPR and licencing options as mediator of relationships in the platform
- Feasibility of a Grace Period system within the system

6.1 LIMITATIONS OF THE RESEARCH RESULTS

As criticised in section 3.7, this thesis has significant limitation of its research design and validity. Such exploratory research on such a complex topic is not recommended for the limited time available for a minor master thesis. The discussions in section 5 and the remarks above should thus be seen as suggestions of findings rather than valid

empirical evidence. The empirical data is however relevant precursors for more limited and thorough studies of the many components explored in this study.

6.2 SUGGESTIONS FOR FURTHER STUDIES

- **Implications of industry-specific "Grace period" of patents in Norwegian marine biotechnology, and in the EPO framework.**
- **Index of various IPR regime performance, by specific innovation systems indicators**
- **Game theory study of industrial actors behaviour at initial access to marine biobank (observational study).**

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APPENDICES

APPENDIX 1: AQUACULTURE SURVEY DESIGN AND FULL RESULTS:

OA (One answer), MA (Multiple answers possible), OE (Open ended).

Question 1: Which public research program funds the project: (MA)

Answer Options	**Response Percent**	**Response Count**
FUGE	37,0%	10
HAVBRUK	63,0%	17
Comments		0
answered question		**18**
skipped question		**1**
total response count		**27**

Question 2: Which field/discipline is your project in? (MA)

Answer Options	**Response Percent**	**Response Count**
Pharmacy	8,0%	2
Animal health/disease	52,0%	13
Genetics	44,0%	11
Nutrition	20,0%	5
Engineering	4,0%	1
Technology	8,0%	2
Other	12,0%	3
answered question		25

total response count	**37**

Question 3: Please describe your type of institution / enterprise in one or more of these terms: (MA)

Answer Options	**Response Percent**	**Response Count**
Profit	28,0%	7
Non-profit	20,0%	5
Private	48,0%	12
Public	24,0%	6
National owners	32,0%	8
International owners	20,0%	5
Primarily research	36,0%	9
Commercial goals	36,0%	9
Other	4,0%	1
answered question		25
total response count		**62**

Question 4: How is your research in general financed? (MA)

Answer Options	**Response Percent**	**Response Count**
Public	20,0%	5
Combined public and industry	48,0%	12
Mainly industry	32,0%	8
Other (please specify)	0,0%	0
answered question		**25**
skipped question		**0**

Question 5: Who gets the ownership of the results in your project? (MA)

Answer Options	**Response**	**Response**

	Percent	Count
Research institute	48,0%	12
Researcher	8,0%	2
Industry project partner	56,0%	14
Other (please specify)	20,0%	5
answered question		**25**
Total responses		**33**

Question 6: Did you have any plans for securing IPR of findings in the project, e.g. through patenting, when you applied for funding? (OA)

Answer Options	Response Percent	Response Count
Yes	39,4%	13
No	60,6%	20
Total responses*		**33**
skipped question		**0**

* Some respondents represented several projects

Question 7: What did you intend to protect? (MA)

Answer Options	Response Percent	Response Count
Product	70,0%	7
Gene, Marker , Organism	70,0%	7
Process	30,0%	3
Method	50,0%	5
answered question		**10**
total response count		**22**

Question 8: Was/Is there a need for protecting new innovations in your project through some type of intellectual property rights (IPR) systems?

(OA)		
Answer Options	**Response Percent**	**Response Count**
Yes	30,3%	10
No	69,7%	23
answered question *		**33**
skipped question		**0**

* Some respondents represented several projects

Question 9: If so, what type of protection (please specify as far as possible) (OE)

- *Only protection is publishing ahead of others -- agreements about that may be necessary some times, when a new method is involved*
- *Maybe protection of candidate vaccines - if any.*
- *If working with universities/institutes or commercial companies agreemsnts have to be signed specifying ownership to IPR. Backgound has to be stated, will be unique for each "party", foreground might be shared. We always wants the rigths to commercial usage of results and IPR*
- *SHould alway be but difficult to manage*
- *new disease agent indentified*

Question 10: If you should plan for an IPR what strategy would you choose (regarding the legal arrangement)? (Rating from 1st – 4th choice)

Answer Options	**1st**	**2nd**	**3rd**	**4th**	**Rating Average**	**Response Count**
Patents	11	4	1	4	2,48	20
Copyright	1	1	2	3	0,56	7
Trade mark and service mark	1	2	3	2	0,72	8
Contracts	4	6	3	3	1,72	16
Tech./biological method	2	2	4	3	1,00	11
I would rather publish	7	3	3	4	1,88	17

I would rather keep it secret	1	3	2	3	0,80	9
Other (please specify) 3 comments						0
Answered question						25
total response count						88

Comments:

- *Order may depend on circumstances / type of finding*
- *This is a very confusing question, I read it as If you were to protect your IP, what strategy would you choose*
- *very strange alternatives!*

Question 11: Do you at this stage have any plans for applying for a patent or did you apply during the project period? (OA)

Answer Options	**Response Percent**	**Response Count**
Yes	16,0%	4
No	84,0%	21
answered question		**25**

Question 12a: How would you describe your reason for applying for a patent in terms of sustainability? (MA) Economic reasons:

Answer Options	**Response Percent**	**Response Count**
protection of the invention	100,0%	4
increased or more stable income, profit or funding for future research	50,0%	2
a patent application would look good at scientific evaluations	25,0%	1
reduction of the losses due to non-authorised use of products	25,0%	1

Other	0,0%	0
answered question		**4**
total response count		**8**

Question 12b: How would you describe your reason for applying for a patent in terms of sustainability? (MA) Environmental and social reasons (MA)

Answer Options	**Response Percent**	**Response Count**
incentives to solve environmental problems	33,3%	1
incentives to solve animal health/welfare problems	66,7%	2
human health/welfare in Norway	0,0%	0
global human health/welfare	0,0%	0
Other	0,0%	0
total response count		**3**

Question 13: What are/was the main reasons for not applying for a patent: (MA)

Answer Options	**Response Percent**	**Response Count**
Immediate publication	15,0%	3
Open/free access	20,0%	4
Secrecy	5,0%	1
Insufficient knowledge and experience	5,0%	1
Demanding process	20,0%	4
Findings not patentable	60,0%	12
Other	15,0%	3
answered question		**20**
total response count		**28**

Question 14: Who would and could apply for a patent from results/output of your project? (MA)		
Answer Options	**Response Percent**	**Response Count**
Industry project partner	79,2%	19
Research intitute	58,3%	14
Other (please specify)	4,2%	1
answered question		**24**
total response count		**34**

Question 15: Do you have experience from earlier IPR practice in other projects? (OA)		
Answer Options	**Response Percent**	**Response Count**
Yes	54,2%	13
No	45,8%	11
answered question		**24**

Question 15 b) If so, could you describe the type of IPR used and whether your experience was positive or negative and how/why? (OE)

1. *Publish to protect others from patenting.*
2. *Have applied for patents, have been stopped by competitors patents from developing products, have out licensed own patents. Both positive and negative implications. Company willing to fund projects when IPR is secured, and of course donn't spend money when patent holder refuses to license.*
3. *We have experiencs with patenting, trade marks, secrecy, publishing. All have their pros and cons.*
4. *Patent. OK experience, though not being the responsible author of the patent.*
5. *IPR regulated in agreements. Not that often findings are patented. We want to secure rights to use tthe results commercially. In cooperation with universities/institutes publication clauses will be used to keep knowledge not public for a reasonable time*
6. *Patent application on using protein toxin target proteins for toxin detection.*

7. *Patent, hemmelighold*

8. *trying to get a patent timeconsuming and costly, still do not know result*

9. *generally negative experience related to patents within aquaculture. The indistry has been too small/immature to handle the patent issue*

10. *As an industry partner we only agree to collaborative research in which we can protect and exclusively own our knowledge. This has been positive because universities and institutes are usually in need of samples and money for students, whereas we need new products and invest heavily in research resources.*

11. *Patent. Both + and - experience. Including court case.*

Question 16: Do you have experience of encountering others' use of IPR that has affected your own research? (OA)		
Answer Options	**Response Percent**	**Response Count**
Yes	45,8%	11
No	54,2%	13
answered question		**24**

Question 16 b): If so, could you please describe how and why? (OE)

- *Competitor holds patent covering all whole virus vaccines against a certain disease, and we are not allowed to market a better product, a public institution holding a patent together with an American university has not reached a license agreement with interested parties to perform a cetain method, so we can not outsource this method. We have inlicensed others IPR in collaborative projects and funded further studies to elucidate if the technology has commercial potential.*

- *A main competitor has a very broad patent hindering development in vaccine development against one specific disease. Another patent holder (a research institute together with an American university) is not able to establish a licence agreement fwith relevant laboratories on a certain method that we would like to outsource, so we have to do the method in house. Very strange use of ip rights!*

- *Patent has been published on the use of carrier system of vaccines, this carrier system is what we explore in the research project.*

- *Protest against patents/patent applications that we think is not valid and will influence use of our products or services*

- *Restriction on use of results for given period (2 years). Researchers may not publish without accwptence from industrial partner.*
- *negative experiences. patents also block research*
- *We compete with other industries to have first and exclusive use of the same knowledge and products. This happens yearly.*
- *Competitors use of own patent*

Question 17: How do you think that strict regulation of IPR (e.g. patents) influences your or others research? (MA)

Answer Options	**Response Percent**	**Response Count**
No influence	25,0%	6
Promotes further research	41,7%	10
Hamper further research	33,3%	8
Comments		5
total response count		**24**

Comments:

- *The answer alternatives to this question are not sufficient. A patent does not stop academic research, but influence who will finance research covered by the patent. A patent holder will have an incentive to do R&D, but all other commercial parties will have a strong incentive for NOT doing R&D in the field. So the answer depends on who is holdng the patent.*
- *It is impossible to give a general answer to this quesition. Some patents hamper our research (if the patent blocks us from developing a certain product there is no point in doing research), if we have a patent it will stimulate our research but stop competitor research. Research is not per se stopped by patents, but of course it will influence who is interested in funding research.*
- *No idea, really*
- *COuld be conflict for RTD and dr students*
- *We will only do collaborative research when our investment can be protected. About 90% of our research is private.*

Question 17: Does your institution/enterprise hold any intellectual property

rights? (OA)		
Answer Options	**Response Percent**	**Response Count**
Yes	62,5%	15
No	8,3%	2
I don't know	29,2%	7
answered question		**24**

Question 17 b): How many? (OE)

- *Several but I don't have the complete overview.*
- *Several patent granted, several patents pending, lots of know how and trade secrets.*
- *120 (inkluderer patentfamilier)*
- *about 25*
- *2*
- *1*
- *do not know*
- *several, difficulty to say how many, because it is related to project RESULTS*
- *Unknown*
- *2 til 3*
- *5*
- *Don't know*
- *many, don't know. Get about 3 new patents per year and also much exclusive licensing.*
- *8 til 10*

Question 17 c): What types? (MA)		
Answer Options	**Response Percent**	**Response Count**

Product	83,3%	10
Gene	25,0%	3
Marker	16,7%	2
Organism	25,0%	3
Process	75,0%	9
Method	58,3%	7
I don't know	8,3%	1
Other	25,0%	3
answered question		**12**
total response count		**38**

Question 18 d) Within which field? (MA)		
Answer Options	**Response Percent**	**Response Count**
Pharmacy	20,0%	3
Animal health/disease	66,7%	10
Genetics	6,7%	1
Nutrition	26,7%	4
Engineering	0,0%	0
Technology	40,0%	6
I don't know	6,7%	1
Other	13,3%	2
answered question		**15**
total response count		**27**

Question 19: Do you hold any intellectual property rights? (OA)		
Answer Options	**Response Percent**	**Response Count**
Yes	17,4%	4
No	82,6%	19

answered question	**23**

Question 19 b) How many? (OE)

- *2*
- *1*
- *1*
- *4*

Question 19 c) What types? (MA)		
Answer Options	**Response Percent**	**Response Count**
Product	0,0%	0
Gene	25,0%	1
Marker	25,0%	1
Organism	0,0%	0
Process	25,0%	1
Method	25,0%	1
Other (please specify)	25,0%	1
answered question		**4**
total response count		**5**

Question 19 d) Within which field? (MA)		
Answer Options	**Response Percent**	**Response Count**
Pharmacy	0,0%	0
Animal health/disease	50,0%	2
Genetics	25,0%	1
Nutrition	25,0%	1
Engineering	0,0%	0

Technology	25,0%	1
Other (please specify)	0,0%	0
answered question		**4**
total response count		**5**

Question 19 e) Describe the strategy and/or chosen arrangement you have made with regard to ownership, control, and protection of IPR? (MA)

Answer Options	**Response Percent**	**Response Count**
Patents	25,0%	1
Copyright	0,0%	0
Trade mark and service mark	0,0%	0
Contracts (e.g. material transfer agreements)	75,0%	3
Other (please specify)	25,0%	1
answered question		**4**
total response count		**5**

Question 20 a): How would you describe your reason for applying for a patent in terms of sustainability? (several answers possible) Economic reasons (Repeat check of Q12 a)

Answer Options	**Response Percent**	**Response Count**
protection of the invention	100,0%	4
increased or more stable income, profit or funding for future research	75,0%	3
a patent application would look good at scientific evaluations	25,0%	1
reduction of the losses due to non-authorised use of products	25,0%	1
		0
answered question		**4**
total response count		**9**

Question 20 b): Environmental and social reasons: (Repeat check of Q12 b)		
Answer Options	**Response Percent**	**Response Count**
incentives to solve environmental problems	0,0%	0
incentives to solve animal health/welfare problems	100,0%	3
human health/welfare in Norway	0,0%	0
global human health/welfare	0,0%	0
		0
answered question		**3**

Question 21: What are the main problems using the IPR that you chose? (MA)		
Answer Options	**Response Percent**	**Response Count**
Do not provide sufficient level of protection	50,0%	2
The keeping of the confidentiality during the procedure	50,0%	2
The long and costly duration of the procedure	25,0%	1
Enforcement and defense of patent right/IPR	25,0%	1
There has not been any problems	0,0%	0
Other	0,0%	0
answered question		**4**
total response count		**6**

Question 22: What are the main reasons for not holding an IPR? (MA)		
Answer Options	**Response Percent**	**Response Count**
Immediate publication of the results	26,3%	5
Free access to my results	36,8%	7
Secrecy	21,1%	4
Insufficient knowledge and experience with the IPR process	0,0%	0

Effort, time and cost demanding process with IPR	26,3%	5
Findings not patentable	63,2%	12
Other	10,5%	2
answered question		19
total response count		35

APPENDIX 2: FULL MARINE BIOTECHNOLOGY CASE STUDY CODING

Code	Informant	Quotes
Funding	NN1	75% Public, 25% Private; Norwegian Research Council, University, industry actors
	NN2	Non-profit, 20 % financed by public funds + 80% Public and private project based
	NN3	Norwegian Research Council (FORNY2020)
	NN4	Public now, potentially combined in the future
	NN5	Public: NFR, FORNY program
	NN6	Private
Function	NN1	Technical platform for analysis and application testing of biological material
	NN2	Project based research institution for public and private interests
	NN3	Business developer, TTO; Commercialization unit for regional public research institutions (University). Negotiate strategies (case based)
	NN4	Leader, Platform of public resource bank
	NN5	Research based innovation, manage the communication with industry
	NN6	IP responsible - attorney
Stage of innovation	NN1	Discovery
	NN2	Application
	NN3	Technology transfer - Facilitator of commercialization
	NN4	Facilitating discovery
	NN5	pre-Discovery - Technology transfer
	NN6	IP management
Experience of innovation diffusion	NN1	Until pre-market testing
	NN2	Product development, application of enzyme
	NN3	Licensed to market stage
	NN4	Discovery
	NN5	Pre-market testing
	NN6	pre- Patent application to final product
Input	NN1	National resource bank, researchers samples
	NN2	Research projects, Public and Private
	NN3	Public research institutions
	NN4	Biological resources
	NN5	Research institutions
	NN6	Commercial actor
Output	NN1	University and private researchers
	NN2	Research projects, Public and private
	NN3	Commercial actors, spin-offs

	NN4	Public research institutions, Industry actors (national and international)
	NN5	Commercial actors
	NN6	Commercial actor
Factors of strategy	NN1	University research strategy and private commercial strategy mixed, global positioning (IP), effective vector to unique finding
	NN2	Project financers strategy, global IP positioning
	NN3	Input institutions and case based commercialization.
	NN4	Broad scope, geography/habitat-based, Global positioning among similar biobanks
	NN5	Research institution strategy
	NN6	Lead compound, uniqueness, positioning to EPO framework
Network	NN1	University researchers, Transfer Technology Office, Industry actors consortium, resource bank
	NN2	R&D institutions, biomarine industry partners
	NN3	Big network represented by the research strategy of the input institutions + IPR agency
	NN4	Industry actors, analysis platforms, research institutions, legal agents
	NN5	Resource bank, analysis platform, synthesis platform, industry actors
	NN6	Other IPR attorneys, Public R&D, TTO
Experience of IP	NN1	Yes, both positive and negative. Mainly positive, efficiency important for early publication (as a researcher)
	NN2	Only positive! But admits partners in general have the opposite view.
	NN3	Highly important in the processes. Patent is cash
	NN4	Do not generate IPR, potential future patenting of processing
	NN5	Yes, patent is the only applicable to the industry
	NN6	Positive experience. Requires competence and preparation
Means of IP	NN1	Patent mainly+ MTA and secrecy
	NN2	Only EPO patents and extended to countries where a product will have market USA; 3 personally, 2 of which inventor. Positive experience
	NN3	Only patenting, pre-patent secrecy
	NN4	Patents and secrecy
	NN5	Patent. Secrecy until patent.
	NN6	Patent, MTA, agreements on secrecy
Technological aspects	NN1	Chemical molecules are preferred for protection, but also biological application.
	NN2	Mainly Enzymes + biological application preferred. Enzyme in general is seldom accepted. Must be very specific (species). Bio Application is ok
	NN3	Important to have broad application rights. Freedom to operate
	NN4	N/A
	NN5	Substance, structures, synthesis + application.
	NN6	Lead compound, high patent, bioprocesses are difficult
Protection preference	NN1	Chemical molecules are preferred - give broader protection, DOFI, Inventors contribution
	NN2	Enzyme, specific, broad is difficult. Journals are readily available for biotechnology facilitating effective global positioning of innovation.

	NN3	Substance is important, this is communicated to researchers = many applications. Time of patenting, global IP positioning, prior art
	NN4	Exclusiveness is important
	NN5	patent. Important to publish as soon as possible (after patent). Must be specific to be efficient
	NN6	Group of patents (cluster), exclusivity of findings is important as investments are big
Innovation of findings	NN1	IP returns to researchers organizations, and to researcher if university do not keep IP
	NN2	IP returns to researcher if the organizations IP group is not interested
	NN3	Very specific selection of partner for licensing. Fields of interest. Patents are kept only in the national stage.
	NN4	Later process of innovation
	NN5	IP directed to an actor within the fields of interest of consortium
	NN6	Finding must be protectable to have commercial potential
Reuse of IP	NN1	No experience of reuse, but will soon join a EU consortium with the aim of knowledge transfer
	NN2	Interest from big international companies about available IP for commercialization, but Nofima prefer cooperation with national smaller partners. No experience of reuse of patent.
	NN3	No experience. Actors are very specific on their needs = Success/fail
	NN4	No experience, but it is planned to be connected to the information from the bank
	NN5	IP returns to university if the IP is not used. In theory it can be reused, but most likely the patent is not of commercial interest
	NN6	No experience: if a patent is not productive - not interesting
Publish vs. Commercialization	NN1	TTO negotiations take too long time, agreement of delaying publication (up to 6 months) if industry actor applies for patent, but not applicable during negotiation of IP
	NN2	Institution will decide whether a finding shall be protected first.
	NN3	Researchers wish to publish as soon as possible, and have the right to it. Negotiations of strategic patenting and licensing can last for some time (up to 6 months)
	NN4	Recognizes the need for researchers publishing. Lack of IPR-experience. Negotiations take time.
	NN5	External researchers can publish, but not within consortium. Duration of patenting vs. Academic progression is a dilemma. Little academic knowledge of IPR
	NN6	Difficult to cooperate with researchers. Reseachers appreciate IP when they are more experienced and credited (by NFR)
Patent evaluation	NN1	Pro: Specific documentation of scientific procedure, Con: Include and balance potential applications of finding
	NN2	Only positive experiences with patents, but admits many others have the opposite perspective. Preparation is important for patent application, good patent agency, global IP positioning
	NN3	Good protection of highly investment costs. The patent system is however made for products and not processes or progression (services). Patents are considered difficult because it is unknown for researchers. IPR agency important
	NN4	Long time of application
	NN5	"What is the alternative?" Process to patent can last long, IPR management. Duration of patent often delayed to gather knowledge for widening the scope, and to include as much pre-

		market testing as possible (before the 20 years duration of patents)
	NN6	Pro: Fair protection and function to lead other researchers to aims of furter investigations, Con: Requires much work when threatened, does not include all inventions (eg. Processes)
Secrecy	NN1	Researchers withhold publication, affects scientific communication (presentations etc.) and education (PhD, other University education)
	NN2	Collaboration between project contractor and organization. Contractor decides secrecy and publication.
	NN3	Essential pre-patent
	NN4	The secrecy and one-directional use is a weakness when the access to resources shall be equal to all
	NN5	All actors within consortium are obliged to secrecy within the patent process
	NN6	Secrecy is crucial pre-patentation
Commercial actors:		
Size and resources	NN1	Significantly mixed
	NN2	Significantly mixed
	NN3	Significantly mix
	NN4	Mixed
	NN5	Significantly mixed - Within consortium and general
	NN6	Significantly mixed
Differentiation	NN1	IP agents, research facilities
	NN2	Resources for agreements on exclusiveness of application of patents (e.g. Licensing, sale or royalties of patent)
	NN3	Pre-market testing require much investment
	NN4	Phase of innovation
	NN5	Capital power. Small companies struggle to maintain the IP
	NN6	Power of innovative strategy, resources for IPR licencing, IP protection
Big actors	NN1	Preferable due to IP-specific requests (strategy), effective patent application
	NN2	Much legal resources for protection of patents and agreements, aim of having a big patent portfolio (for investors)
	NN3	End-market oriented. Pre-market testing. Much resources for IPR protection. Open about their interests.
	NN4	Resources for end-market commercialization. International.
	NN5	Shop IP and startups. IP shopping secures broad scope of market.
	NN6	More specific. Tend to buy IP from startups and develop the ideas (less focus on research)
Small actors	NN1	Less IP-experience, apply for broader patents=rejection, require more resources from researchers for patent application
	NN2	Less legal resources. Will rather get licenses for patents than buying.
	NN3	Norwegian actors, develop an application.
	NN4	Costs of exploration and analysis
	NN5	Business strategy :Develop a lead compound for sale to bigger companies

	NN6	Less specific. Basal research, no resources for innovation diffusion or IP protection in high tech industries
Various comments:		Timing of patenting and licensing is essential for maximum progress in duration
		The value of a patent is limited by your ability to defend it in court. Who is responsible; Small actors with IPR, University as IP holder?
		Information on patents and publications shall be included in the resource bank (innovation platform)
		Uncertain legal strategy for the institution
		* Hearing => General public can access the information
		Field of interest within consortium
		Licensing; mainly "milestones", royalty fee (3-4%), less "lead compound"
		"What can you sell, if you do not have patents?"
		University hold patents for licensing is utopic, the resources needed for IPR management is too great and complex
		A-priori MTAs and licensing agreements are highly complex Grace period: "US system of 1 year of IP protection post publication should be applied in Norway" Joint Ventures are not very applicable to biotechnology, as the research is specific and compound-oriented, and will not benefit two parties with different aims. IPR in biotechnology is too complex for the average actor/researcher. Easier framework for patent applications will spur more protection, and thus willingness to innovate.

APPENDIX 3: 11 STEPS OF THE PATENT FILING PROCEDURE (EUROPEAN PATENT ORGANISATION):

1 Before applying for a European patent

First, it is important to know what inventions and patents are.

An invention can be, for example, a product, a process or an apparatus. To be patentable, it must be new, industrially applicable and involve an inventive step.

Patents are valid in individual countries for specified periods. They are generally granted by a national patent office, or a regional one like the EPO. Patents confer the right to prevent third parties from making, using or selling the invention without their owners' consent.

Patents should not be confused with the other kinds of intellectual property rights available:

- Utility models can be registered in some countries, to protect technical innovations which might not qualify for a patent
- Copyright protects creative and artistic works such as literary texts, musical compositions and broadcasts against unauthorised copying and certain other uses
- Trade marks are distinctive signs identifying brands of products or services; they may be made up of two- or three-dimensional components such as letters, numbers, words, shapes, logos or pictures, or even sounds
- Designs and models protect a product's visual appearance, i.e. its shape, contours or colour.

Before applying for a patent, it is advisable to carry out a patent search.

2 Application

There are different routes to patent protection and the best route for you will depend on your invention and the markets your company operates in. The European Patent Office accepts applications under the European Patent Convention (EPC) and the Patent Cooperation Treaty (PCT). If you are seeking protection in only a few countries, it may be best to apply direct for a national patent to each of the national offices.

A European patent application consists of:

- a request for grant
- a description of the invention
- claims

- drawings (if any)
- an abstract.

Applications can be filed at the EPO in any language. However, the official languages of the EPO are English, French and German. If the application is not filed in one of these languages, a translation has to be submitted. Although the services of a professional representative are mandatory only for applicants residing outside Europe, the EPO advises all applicants to seek legal advice.

3 Filing and formalities examination

The first step in the European patent granting procedure is the examination on filing. This involves checking whether all the necessary information and documentation has been provided, so that the application can be accorded a filing date.

The following are required:

- an indication that a European patent is sought
- particulars identifying the applicant
- a description of the invention or
- a reference to a previously filed application.

If no claims are filed, they need to be submitted within two months.

This is followed by a formalities examination relating to certain formal aspects of the application, including the form and content of the request for grant, drawings and abstract, the designation of the inventor, the appointment of a professional representative, the necessary translations and the fees due.

4 Search

While the formalities examination is being carried out, a European search report is drawn up, listing all the documents available to the Office that may be relevant to assessing novelty and inventive step. The search report is based on the patent claims but also takes into account the description and any drawings. Immediately after it has been drawn up, the search report is sent to the applicant together with a copy of any cited documents and an initial opinion as to whether the claimed invention and the application meet the requirements of the European Patent Convention.

5 Publication of the application

The application is published - normally together with the search report - 18 months after the date of filing or, if priority was claimed, the priority date. Applicants then have six months to

decide whether or not to pursue their application by requesting substantive examination. Alternatively, an applicant who has requested examination already will be invited to confirm whether the application should proceed. Within the same time limit the applicant must pay the appropriate designation fee and, if applicable, the extension fees. From the date of publication, a European patent application confers provisional protection on the invention in the states designated in the application. However, depending on the relevant national law, it may be necessary to file a translation of the claims with the patent office in question and have this translation published.

6 Substantive examination

After the request for examination has been made, the European Patent Office examines whether the European patent application and the invention meet the requirements of the European Patent Convention and whether a patent can be granted. An examining division normally consists of three examiners, one of whom maintains contact with the applicant or representative. The decision on the application is taken by the examining division as a whole in order to ensure maximum objectivity.

7 The grant of a patent

If the examining division decides that a patent can be granted, it issues a decision to that effect. A mention of the grant is published in the European Patent Bulletin once the translations of the claims have been filed and the fee for grant and publication have been paid. The decision to grant takes effect on the date of publication. The granted European patent is a "bundle" of individual national patents.

8 Validation

Once the mention of the grant is published, the patent has to be validated in each of the designated states within a specific time limit to retain its protective effect and be enforceable against infringers. In a number of contracting states, the patent owner may have to file a translation of the specification in an official language of the national patent office. Depending on the relevant national law, the applicant may also have to pay fees by a certain date.

9 Opposition

After the European patent has been granted, it may be opposed by third parties – usually the applicant's competitors – if they believe that it should not have been granted. This could be on the grounds, for example, that the invention lacks novelty or does not involve an inventive

step. Notice of opposition can only be filed within nine months of the grant being mentioned in the European Patent Bulletin. Oppositions are dealt with by opposition divisions, which are normally made up of three examiners.

10 Limitation / revocation

This stage may also consist of revocation or limitation proceedings initiated by the patent proprietor himself. At any time after the grant of the patent, the patent proprietor may request the revocation or limitation of his patent. The decision to limit or to revoke the European patent takes effect on the date on which it is published in the European Patent Bulletin and applies *ab initio* to all contracting states in respect of which the patent was granted.

11 Appeal

Decisions of the European Patent Office – refusing an application or in opposition cases, for example – are open to appeal. Decisions on appeals are taken by the independent boards of appeal. In certain cases it may be possible to file a petition for review by the Enlarged Board of Appeal.